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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte KENNETH WILLIAM HUNT and KEITH PATRICK HEATON

Appeal No. 2004-_____
Application No. 09/807,403
Filed: July 2, 2001
Group Art Unit: 3761
Examiner: Truong, Linh T.
Title: NEGATIVE PRESSURE USING WALL SUCTION
Confirmation No.: 9206
Attorney Docket No.: VAC.705.US

APPELLANTS' AMENDED APPEAL BRIEF

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I. Real Party in Interest

KCI Licensing, Inc., is the assignee of the pending application. KCI Licensing, Inc., and the related publicly traded company Kinetic Concepts, Inc., of San Antonio, Texas (ticker: KCI) are the real parties in interest.

II. Related Appeals and Interferences

Appellants, Appellants' legal representative, and KCI Licensing, Inc., are not aware of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-15 are pending in the application. Claims 1, 8 and 14 are independent. Claims 2-7, 12 and 13 depend directly or indirectly from claim 1. Claims 9-11 depend directly or indirectly from claim 8, and claim 15 depends directly from claim 14. Each of claims 1-15 has been rejected. And Applicants appeal the rejections of each of claims 1-15.

IV. Status of Amendments

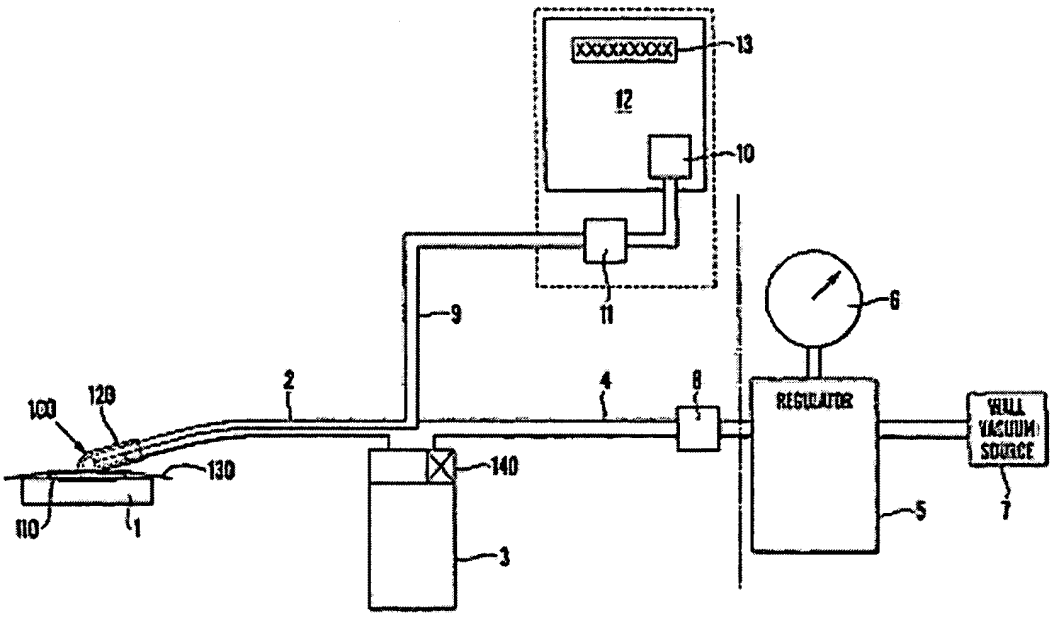
No amendments to claims 1-15 were filed subsequent to the final rejection dated May 10, 2004.

V. Summary of the Claimed Subject Matter

The pending patent application discloses an apparatus for applying negative pressure wound therapy to a wound site. There are three independent claims pending: 1, 8 and 14, which in compliance with 37 C.F.R. §41.37(c)(1)(v) are summarized below.

A. Independent Claim 1

The apparatus for applying negative pressure therapy to a wound site comprises an open celled foam pad (ref. 1, p. 4, line 7, FIG. 1 or 2) for application to the wound, a suction tube (ref. 2, p. 4, line 8. FIG. 1 or 2) connecting the foam pad to a collection canister (ref. 3, p. 4, line 8, FIG. 1 or 2) having a shut-off valve (ref. 140, p.4, line 9, FIG.1), which closes the outlet from the canister when it is full, a tube (ref. 4, p.5 line 6, FIG. 1 or 2) for connecting the canister to a wall suction point (ref. 7, p.5. line 8, FIG. 1 or 2) or to a vacuum bottle (p. 2, line 18), and a pressure detecting device (ref. 10, p. 5, line 14) connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level. An embodiment of this is shown in FIGURE 1, reproduced herein below.



B. Independent Claim 8

The apparatus for applying negative pressure therapy to a wound site comprises an open celled foam pad (ref. 1, p. 4, line 7, FIG. 1 or 2) for application to the wound, a suction tube (ref. 2, p. 4, line 8. FIG. 1 or 2) connecting the foam pad to a collection canister (ref. 32, p. 6, line 20, FIG. 2), a tube (ref. 4, p.5 line 6, FIG. 1 or 2) for connecting the canister to a wall suction point (ref. 7, p.5. line 8, FIG. 1 or 2) or to a vacuum bottle (p. 2, line 18), and a sensor (ref. 34, p. 6, line 21, FIG. 2) operable to detect when the canister is full.

C. Independent Claim 14

The apparatus for applying negative pressure therapy to a wound site comprises an open celled foam pad (ref. 1, p. 4, line 7, FIG. 1 or 2) for application to the wound, a suction tube (ref. 2, p. 4, line 8. FIG. 1 or 2) connecting the foam pad to a collection canister (ref. 32, p. 6, line 20, FIG. 2), a tube (ref. 4, p.5 line 6, FIG. 1 or 2) for connecting the canister to a wall suction point (ref. 7, p.5. line 8, FIG. 1 or 2) or to a vacuum bottle (p. 2, line 18), and a processor (ref. 12, p. 6, line 8) in electronic communication with the pressure regulator to regulate the pressure from the wall suction point or vacuum bottle.

VI. Grounds of Rejection to be Reviewed on Appeal

A. Is claim 14 unpatentable because of informalities?

B. Are claims 8-11 unpatentable under 35 U.S.C. §103(a) over Lina et al. in view of Applicant's own admission?

C. Are claims 8-10 unpatentable under 35 U.S.C. §102(b) as being anticipated by Hunt et al. and in view of Applicant's own admission (i.e. is a 102(b) rejection properly made when using a *combination* of references)?

D. Are claims 14 and 15 unpatentable under 35 U.S.C. §102(b) as being anticipated by Hunt et al. and in view of Applicant's own admission (i.e. is a 102(b) rejection properly made when using a *combination* of references)?

E Is claim 11 unpatentable under 35 U.S.C. §103(a) over Lina et al. in view of Applicant's own admission and further in view of Cover et al.?

F. Is claim 11 unpatentable under 35 U.S.C. §103(a) over Hunt et al. in view of Applicant's own admission and further in view of Cover et al.?

G. Are claims 1, 3-7, and 12-13 unpatentable under 35 U.S.C. §103(a) over Lina et al. in view of Applicant's own admission, in view of Nichols and in further view of Hunt et al.?

H. Is claim 2 unpatentable under 35 U.S.C. 103(a) over Lina et al. in view of Applicant's own admission, in view of Nichols, in view of Hunt et al., and in further view of Dixon et al.?

Lina et al., Hunt et al., Nichols, Dixon et al., Peterson et al, and Cover et al. are attached hereto as Exhibits 1, 2, 3, 4, 5 and 6 respectively in the Evidence Appendix. These patents were relied upon by the Examiner as to grounds of rejection to be reviewed in the present appeal.

VII. Argument

This appeal comes in response to the final second office action on the merits rejecting the claims. In the first of these office actions, the Examiner rejected all of the pending claims over commonly-owned EP 0 853 950 to Lina et al., entitled "Wound Drainage Canister," in combination with other references. As the prosecution progressed, the Examiner withdrew some of these grounds of rejection in view of various arguments and amendments that were made. But in every case, new grounds of rejection involving other combinations of art replaced the withdrawn grounds of rejection. Lina et al. have been the key reference of almost every ground of rejection.

The Lina et al. reference is concerned with the controlled collection of wound drainage in a canister during the application of negative pressure wound therapy to a wound. A portable suction pump 10 as described in Lina et al. is *required* for negative pressure wound therapy treatment of wounds, due to the controlled and extensive application of negative pressure to the wounds as described in Lina et al. Absent the novel control features described in Lina et al., dangers to the patient, such as exsanguination, are difficult to avoid. *See* col 11, l. 26 – col. 12, l. 55 of Lina et al. for a detailed description of the control features disclosed therein. In the event of a bleed out during application of negative pressure therapy to the wound, the invention of Lina et al. would alert caregivers or otherwise help reduce the risks associated with this adverse event. Lina et al. describes the use of a portable suction pump 10 for use with its canister 19 instead of wall suction. While the Examiner has interpreted this feature as the portable suction pump being interchangeable with wall suction, this is simply not the case.

First, Lina et al. is directed to a *portable* wound closure apparatus with a small, compact and easily portable carrying case.[1] The present invention is directed to a device that can be used to provide negative pressure therapy on connection to an *existing* source of suction, such as a vacuum line.[2] The device of Lina et al. provides mobility of the patient so that he is not confined to one particular place while the therapy is in progress, whereas the device of the present invention, which satisfies a demand, is directed to a more basic piece of equipment that overcomes problems of inadequate hospital staff for close supervision, and reduction in the danger of patient injury.[3]

Second, the device of Lina et al. necessarily includes a complex control system 70, which serves all sorts of functions from preventing users from operating wound closure apparatus 10 without a canister properly installed, to a tilt sensor 72 to prevent operation if the apparatus 10 is tilted excessively, to the fill sensor 64 to deactivation of the pump motor 83.[4]

The very purpose of the present invention is to provide equipment that can be used with an existing wall suction source to safely provide negative pressure therapy to patients, accomplished by utilizing existing wall suction with simplified control schema.

Because of the immobility of the present invention, one would not look to the disclosure of the portable device of Lina et al. to find a solution that enhances patient safety while utilizing existing sources of suction. There is simply no motivation anywhere in Lina et al. Moreover, the purpose of Lina et al. (mobility) would be

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[1] Col. 3, ll. 29-39.

[2] Page 1, first paragraph. See also page 2, 2nd full paragraph.

[3] Page 1 last paragraph.

[4] Lina et al., col 12.

destroyed by the use of wall suction (immobility) in combination with the device of Lina et al. Finally, many of the advantages of Lina et al. (control system 70) would be lost in the selective combination of certain elements (sans control system 70) to arrive at the claims of the present invention.

A. Claim 14, as amended, is patentable.

In the final office action May 10, 2004, the Examiner objected to claim 14 as containing informality, and suggested correction. Applicants do not contest this objection, and submits herewith an amended claim 14 with the appropriate correction. In claim 14, line 6, the phrase should have read "a pressure regulator connected **to** the tube..." with the missing text in bold. Applicants would like to add that text during this appeal to remove the objection. No new matter has been added.

B. Claims 8-11 are patentable over Lina et al. in view of Applicant's own admission.

The Examiner rejected claims 8-11 under 35 U.S.C. § 103(a) as being unpatentable over Lina et al. in view of Applicant's owned admission. The Examiner reasoned that "Lina teaches a wound drainage apparatus comprising an open-celled pad 36, suction tubes 37,38 connecting the pad 36 to a collection canister 19, a tube 62 connecting the canister 19 to a vacuum pump **instead of** connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51) and a fill sensor 64 for sensing when the container is filled and shutting off the vacuum (col. 12, lines 13-19)." Final Office Action, page 3 (emphasis in original). The Examiner further reasoned "waste canisters are well known in the art, and as admitted by Applicant in the specification (p.5. lines 3-10), to be hooked up to "standard hospital wall suction source" or "...an existing suction source..." (vacuum bottles are well known "...existing suction

sources...")."[5] *Id.* The Examiner concluded it to be "obvious to one of ordinary skill in the art at the time the invention was made to provide the invention of Lina with a wall suction source or a vacuum bottle for a limitless or inexpensive, respectively, suction source."[6]

For at least the reasons set forth below, this ground of rejection cannot stand.

1. Claim 8 is patentable over Lina et al. *regardless* of Applicant's admission

The Federal Circuit unequivocally "forbids the use of hindsight in the selection of references that comprise the case of obviousness."[7] And "[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."[8] Hindsight alone inspired the Examiner's conclusion, and this is unsupported by case law and the present application elements.

"Most if not all inventions arise from a combination of old elements."[9] "If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue."[10] The Federal Circuit has time and

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[5] Applicant respectfully asserts that it is uncertain exactly what this fragmented sentence means, but for purposes of clarity, it is treated as being a complete sentence.

[6] Final Office Action, at 3.

[7] *In re Rouffet*, 149 F.3d 1350 at 1358 (Fed.Cir. 1998).

[8] *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986).

[9] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

[10] *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

again categorically rejected the mere-combinations-cannot-be-patented concept underlying the Examiner's rejection of the instant application's claims.[11]

Interestingly, the Examiner's no-patents-for-mere-combinations position heralds back to a bygone era famous for its inhospitality to patents. In 1950, the Supreme Court held that claims involving combinations of known elements could not be patented unless "the whole in some way exceeds the sum of its parts" and the combination yields some "unusual or surprising result."[12] Fortunately, this rule was overturned with the passage of the 1952 Patent Act and the Supreme Court's 1964 *Graham* decision. Since then, the Federal Circuit and its predecessor courts "have considered and rejected the notion that a new result or function or synergism is a requirement of patentability."[13] As the Federal Circuit explained in *Chore-Time Equip., Inc. v. Cumberland*, such a requirement has no basis in the text of the Patent Act:

> A requirement that an invention reflect 'synergism' or achieve a 'synergistic result,' before it may be held patentable appears nowhere in the statute, 35 U.S.C. The test of obviousness under 35 U.S.C. § 103, as the statute makes plain, is whether the invention as a whole would have been obvious at the time it was made to one of ordinary skill in the art.[14]

It is valuable to revisit the rationale for making patent protection *readily* available to innovators for their advancements and improvements on the prior art. Readily

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[11] *See, e.g., Fromson v. Advance Offset Plate*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (holding that "[t]here is no basis in the law . . . for treating combinations of old elements differently in determining patentability" than any other claim).

[12] *Great Atlantic and Pacific Tea Co. v. Supermarket Eq. Corp.*, 340 U.S. 147, 152 (1950).

[13] *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984).

[14] *Chore-Time Equip., Inc. v. Cumberland*, 713 F.3d 774, at 781 (Fed. Cir. 1983).

available protection spurs investment in innovation. Making patent protection exceptionally difficult to obtain and enforce will discourage such investments.[15]

Novel combinations of old elements cannot be rejected as obvious merely because they are combinations of old elements. "[I]nvention itself is the process of combining prior art in a nonobvious manner."[16] The mere fact that the prior art *can* be combined or modified does not render the resultant combination or modification obvious.[17] "The critical inquiry is whether 'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination."[18] Although a prior art reference "may be capable of being modified to run the way [an] apparatus is claimed, there must be a suggestion or motivation in the reference to do so."[19]

To sustain an obviousness rejection, an examiner "must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed."[20] More particularly, the examiner "must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination."[21] The Federal Circuit requires "rigorous application of the

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[15] Conversely, it is true that monopolies discourage competition. But the Patent Act, as required by the Constitution, strikes the balance between encouraging innovation and promoting competition by preserving the exclusive right for only a "limited time."

[16] *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998).

[17] *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

[18] *Fromson v. Advance Offset Plate*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (quoting *Lindeman Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984).

[19] *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990) (emphasis added).

[20] *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (emphasis added).

[21] *Id.* at 1359.

requirement for a showing of the teaching or motivation to combine prior art references" as an antidote to "the subtle but powerful attraction of a hindsight-based obviousness analysis."[22]

Because none of the cited references supply any motivation, teaching, or suggestion for combining Lina et al. with Applicant's admission regarding wall suction sources or vacuum bottle suction source, the invention of claim 8 is submitted to be in condition for allowance. In reality, the portability of the Lina et al. device *inherently teaches away* from the immobility of the present invention when used with wall suction. Moreover, the complexity required for a portable pump system, as described in Lina et al., would unnecessarily require the addition of many unneeded parts therein if properly combined. For these reasons and the reasons set forth in the "ARGUMENT" section above, the present invention is submitted to be novel and non-obvious in view of the cited art.

2. Claims 9-10, dependent on claim 8, are likewise allowable

It is well established that if a base claim is patentable over the prior art, then its dependent claims are also patentable over the prior art.[23] Claims 9 and 10 depend from claim 8. Therefore, claims 9 and 10 are patentable over Lina et al. in view of Applicant's own admission for all of the previously expressed reasons that claim 8 is patentable over the cited references.

3. The rejection of Claim 11 is incoherent such that Applicant cannot respond

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[22] *In re Dembiczak*, 175 F.3d at 999 (Fed.Cir. 1999) (emphasis added).

[23] *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

It is well established that if a base claim is patentable over the prior art, then its dependent claims are also patentable over the prior art.[24] Claims 11 depends from claim 8. Therefore, claim 11 is patentable over Lina et al. in view of Applicant's own admission for all of the previously expressed reasons that claim 8 is patentable over the cited references.

Moreover, Applicant takes exception to the rejection of claim 11.[25] Given the incoherent rejection statement, Applicant is unsure how to respond, and requests this rejection be withdrawn.

4. Lina et al. is not properly combined with the admission of the present invention.

Lina et al.'s teachings also do not suggest and cannot withstand a combination with the present application. Lina et al. is directed to a *portable* apparatus, whereas the present invention is adapted for patients in hospital settings and largely *immobile.*

Applicants dispute the Examiner's conclusion that it would have been obvious to one of ordinary skill in the art "to provide the invention of Lina with a wall suction source or a vacuum bottle for a limitless or inexpensive, respectively, suction source."[26] But when one takes the teachings of Lina et al. and the present invention admissions "as a whole," without the benefit of hindsight, no motivation, teaching, or suggestion can be found for modifying the portable device of Lina et al. by the combination of a *non-*

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[24] *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

[25] The rejection stated: "For claim 11, [*sic*] teaches a keypad that have various vacuum pressures that a user can choose (col. 9, lines 35-46) over the pressure that is presently displayed/present between the canister and the vacuum source." Applicant is unsure what is meant by this rejection (i.e., *what* teaches a keypad?), and therefore objects to this rejection inasmuch as the Applicant cannot be expected to present a response to a rejection that is at the least grammatically incorrect, lacking a subject. For the reasons stated above, however, claim 11 is submitted to be allowable over Lina et al. and applicant's own admission.

[26] Final Office Action, at 3.

portable wall suction source as taught in the present invention. The Examiner's conclusion was based on forbidden hindsight.

C. Claims 8-10 were improperly rejected under 35 U.S.C. §102(b) as being anticipated by Hunt et al. and in view of Applicant's own admission.

The Examiner rejected claims 8-10 "under 35 U.S.C. 102(b) as being anticipated by Hunt et al. 'WO 9718007 (IDS) and in view of Applicant's own admission."[27] This is respectfully submitted to be an improper rejection, and Applicant requests its withdrawal. The standard for lack of novelty is one of strict identity. To anticipate a claim for a patent, a *single prior source* must contain all its essential elements.[28] The Examiner cites two different references, and therefore provides Applicant with an inappropriate rejection. The Examiner further citing Lina et al. in the discussion of the rejection confounds this even more.[29]

Accordingly, claim 8-10 is submitted to be in condition for allowance, and this rejection is respectfully requested to be withdrawn for improper form.

D. Claims 14-15 were improperly rejected under 35 U.S.C. §102(b) as being anticipated by Hunt et al. and in view of Peterson et al.

The Examiner rejected claims 14-15 under 35 U.S.C. §102(b), which is an improper rejection for the same reasons as described above. Namely, the Examiner has improperly combined two references (Hunt et al. in view of Peterson et al.) for a 102(b) rejection. Moreover, the Examiner cited Lina et al. during the discussion of the

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[27] Final Office Action, at 4.

[28] *See Herman v. William Brooks Shoe Co.*, 54 USPQ2d 1046 (S.D.N.Y. 2000); *see also* 35 U.S.C. §102(b).

[29] Final Office Action, at 4.

rejection without stating that these claims were anticipated by Lina et al. in the rejection line of the Final Office Action.[30]

Accordingly, due to the improper form of the rejection, claims 14-15 are submitted to be allowable, and this improper rejection is respectfully requested to be withdrawn.

E. Claim 11 is patentable under 35 U.S.C. §103(a) over Lina et al. in view of Applicant's own admission and further in view of Cover et al. because the selected features of these isolated references are not properly combined together.

The Examiner rejected claim 11 under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of applicant's own admission, and in further view of Cover et al. This rejection fails for the same reasons expressed in the Argument section, and section B(4), above.

F. Claim 11 is patentable under 35 U.S.C. §103(a) over Hunt et al. in view of Applicant's own admission and further in view of Cover et al.

The Examiner rejected claim 11 under 35 U.S.C. §103(a) as being unpatentable over Hunt et al. in view of applicant's own admission, and in further view of Cover et al. Like Lina et al. Hunt is directed to a "Portable Wound Treatment Apparatus", which is completely opposite than that of the largely immobile invention of claim 11, which utilizes wall section. Accordingly, the same arguments with respect to Lina et al. described above apply. This rejection fails for the same reasons expressed in the

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[30] Final Office Action, at 5.

Argument section, and section B(1), above. Namely, there is no motivation, suggestion or teaching in Hunt et al. or Cover et al. that would result in the invention of claim 11.

G. Claims 1, 3-7, and 12-13 are patentable under 35 U.S.C. §103(a) over Lina et al. in view of Applicant's own admission, in view of Nichols and in further view of Hunt et al.

The Examiner rejected claim 1, 3-7 and 12-13 as being unpatentable over Lina et al. in view of Applicant's own admission, in view of Nichols, and in further view of Hunt et al. This rejection fails for the same reasons expressed in the Argument section, and section B, above. In particular, it is clearly evident that the Examiner is merely picking and choosing elements in the prior art because of the mere fact that the prior art *can* be combined or modified, which does not render the resultant combination or modification obvious.[31] As stated in section B, above, "The critical inquiry is whether 'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination."[32] Although a prior art reference "may be capable of being modified to run the way [an] apparatus is claimed, there must be a suggestion or motivation in the reference to do so."[33]

To sustain an obviousness rejection, an examiner "must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art

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[31] *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

[32] *Fromson v. Advance Offset Plate*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (quoting *Lindeman Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984)).

[33] *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990) (emphasis added).

references for combination in the manner claimed."[34] More particularly, the examiner "must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination."[35] The Federal Circuit requires "rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references" as an antidote to "the subtle but powerful attraction of a hindsight-based obviousness analysis."[36]

This rejection is nothing more than hindsight-based obviousness analysis. The Examiner has not provided any rationale or rule as to what would make one of ordinary skill in the art combine these references, much less any motivation therefor. Accordingly, claim 1 is submitted to be allowable over the cited art, and its dependent claims 3-7, and 12-13 are likewise submitted to be allowable.

H. Claim 2 is allowable under 35 U.S.C. §103(a) as being patentable over Lina et al. in view of Applicant's own admission, in view of Nichols, in view of Hunt et al. and in further view of Dixon et al.

The Examiner statement pertaining to claim 2, "in addition to the 103(a) rejection of claim 1 above...[i]t is well known in the aspiration art to have a flow limiting valve for regulating the flow of vacuum"[37], like the rejection identified in section G above and in section B above, fails for the same reasons: there is nothing in Dixon et al. to suggest the combination of a flow-limiting valve into a negative pressure wound therapy device

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[34] *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (emphasis added).

[35] *Id.* at 1359.

[36] *In re Dembiczak*, 175 F.3d at 999(Fed.Cir.1999) (emphasis added).

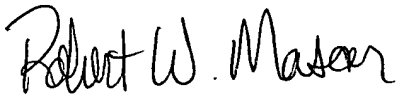
[37] Final Office Action, at 9.

as of that in dependent claim 2. Accordingly, claim 2 is submitted to be in condition for allowance.

Conclusion

Appellants have shown that the prior art lacks any teaching, suggestion or motivation to make the claimed combinations. In addition, Appellants have shown several rejections to be improper, confusing, grammatically incorrect or incoherent. For the foregoing reasons, Appellants believe that the Examiner's rejections of Claims 1-15 were erroneous and/or improper, and reversal of the decision is respectfully requested.

Respectfully submitted,



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CLAIMS APPENDIX

1. Apparatus for applying negative pressure therapy to a wound site, which comprises an open celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, said canister having a shut-off valve which closes the outlet from the canister when it is full, a tube connecting the canister to a wall suction point or to a vacuum bottle, and a pressure detector connected to the suction tube between the foam pad and the canister for indicating when the pressure in the suction tube crosses a predetermined level.

2. Apparatus as claimed in claim 1 which includes a flow limiting valve disposed between the canister and the suction source.

3. Apparatus as claimed in claim 1 which includes a pressure relief valve which is connected to the suction tube between the foam pad and the canister.

4. Apparatus as claimed in claim 1, further comprising a first transducer for measuring pressure in the tube linking the canister to the wall suction point or to a vacuum bottle, and wherein the pressure detector connected to the suction tube between the foam pad and the canister comprises a second transducer.

5. Apparatus as claimed in claim 1 which includes a flow rate meter for measuring the rate at which fluid is sucked from the wound site.

6. Apparatus as claimed in claim 5 in which the flow rate meter measures the rate at which the canister is filled.

7. Apparatus as claimed in claim 6 in which the flow rate meter is an electrical capacitance measuring device.

8. Apparatus for applying negative pressure therapy to a wound site, which comprises an open-celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, a tube connecting the canister to a wall suction point or a vacuum bottle and a sensor operable to detect when the canister is full.

9. Apparatus according to claim 8 which includes means for giving a warning that the canister is full and/or shutting off the connection between the canister and the wall suction point.

10. Apparatus according to claim 8 which further includes means for monitoring pressure at the wound site.

11. Apparatus according to claim 8 which further includes means for regulating pressure between the canister and the suction source.

12. Apparatus as claimed in claim 1 in which the pressure detector comprises a transducer connected by a branch tube to the suction tube leading from the foam pad to the canister.

13. Apparatus as claimed in claim 3, further comprising a processor operationally coupled to the relief valve and programmed to provide intermittent negative pressure therapy to the wound site.

14. Apparatus for applying negative pressure therapy to a wound site, the apparatus comprising:

an open-celled foam pad for application to the wound;

a suction tube connecting the foam pad to a collection canister;

a tube for connecting the canister to a wall suction point or a vacuum bottle;

a pressure regulator connected the tube for connecting the canister to said wall suction point or vacuum bottle; and

a processor in electronic communication with the pressure regulator to regulate the pressure from said wall suction point or vacuum bottle.

15. The apparatus of claim 14, wherein the pressure regulator includes a relief valve, and wherein the processor is configured to actuate the relief valve to relieve pressure at the wound site when pressure at the wound site reaches a set maximum pressure.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte KENNETH WILLIAM HUNT and KEITH PATRICK HEATON

Appeal No. 2004-_____
Application No. 09/807,403

EVIDENCE APPENDIX TO APPELLANTS' BRIEF

Reference ..... Exhibit Number

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(54) Wound drainage canister

(57) A canister (19) is used for collecting wound fluids in a wound treatment apparatus comprising a wound dressing pad and a suction pump (10) for applying negative pressure to the wound dressing pad. The canister comprising a moulded plastics container (19) having an inlet (35) for connection to wound dressing pad (36) and an outlet (52) for connection to suction pump 10, said outlet incorporating a bacterial filter (46). The canister is part of a sealed sterile pack in which the inlet (35) is sealed to a drainage tube (38) and the drainage tube is connected to a porous pad (36) of open-celled reticulated foam having more than 90% of interconnecting cells.

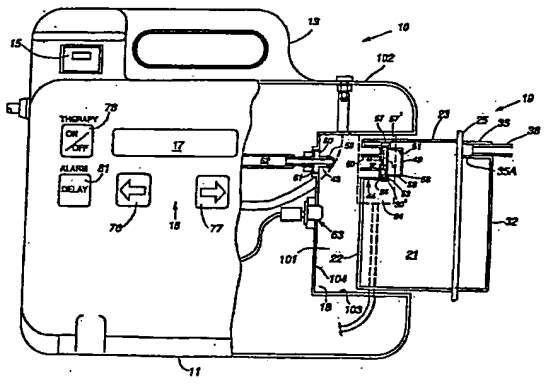

FIG.6

EP 0 853 950 A1

Description

The present invention relates to the healing of wounds and, more particularly, but not by way of limitation, to a disposable wound fluids canister apparatus for closing wounds.

Wound closure involves epithelial ad subcutaneous tissue adjacent the wound migrating towards the centre of the wound until it closes. Unfortunately, closure is difficult with large wounds or wounds that have become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound. Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and, thus are less able to close the wound naturally. Such wounds have presented difficulties to medical personnel for many years.

The most common technique for closing open wounds has been the use of sutures or staples. Although such mechanical closure techniques are widely practised and often effective, they suffer a major disadvantage by providing tension on the skin tissue adjacent the wound. That is, the tensile force required to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. Such stresses commonly result in the rupture of the tissue at those points, which can eventually cause dehiscence in wounds, providing additional tissue loss.

Moreover, some wounds harden and inflate to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalisation, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds, decubitus ulcers, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

The above problem is discussed in WO 93/09727 which proposes as a solution a procedure for draining the wound by applying a continuous negative pressure to the wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound. Although WO 93/09727 deals in some detail with the clinical considerations of this kind of treatment, the apparatus described has certain practical shortcomings.

One problem with the apparatus described in the above prior document is that no means are disclosed for avoiding spread of infection from one patient to another or re-infection of the patient being treated.

WO 96/05873 discloses a therapeutic apparatus for stimulating healing of wounds, said apparatus including a housing that contains a vacuum pump and a chamber for holding a disposable wound drainage collection canister. The canister preferably resides within the chamber and connects at an outlet with the vacuum pump and at an inlet with a porous pad. The pad is placed over a wound and adhesively secured thereto to create a sealed environment at the wound. Thus, when the vacuum pump activates, it evacuates air from the canister and thence the wound environment, resulting in the application of negative pressure to the wound, which in turn tends to promote drainage of fluids flowing from the wound into the canister. After the canister is filled, it is removed from the chamber, disposed of, and replaced with another canister to continue therapy.

Although the vacuum pump is designed to be reusable because of its more costly components, the apparatus utilizes a removable and disposable canister adapted to prevent contamination of the vacuum pump or the remainder of the apparatus. If the vacuum pump or other parts of the housing or the tubing leading to the pump from the canister became contaminated, the wound closure apparatus would have to be completely disassembled, thoroughly cleaned and possibly discarded. Disassembly and cleaning of the wound closure apparatus is extremely time and labour intensive, while disposal of the wound closure apparatus is expensive. Consequently, a removable and disposable canister prevents either of the above undesirable circumstances from occurring.

The present invention is divided out of the disclosure of WO96/05873.

It is an object of the present invention to provide a removable and disposable wound fluids collection canister to protect the wound closure apparatus from contamination.

The present invention provides a canister for use in wound treatment apparatus comprising a wound dressing pad and a suction pump for applying negative pressure to the wound dressing pad, said canister comprising a moulded plastics container having an inlet for connection to a wound dressing pad and an outlet for connection to a suction pump, said outlet incorporating a bacterial filter.

In a preferred configuration, the present invention provides a sterile pack for use in wound treatment apparatus, which comprises a canister for collecting fluids sucked from a wound, said canister having an inlet, which is sealed to a drainage tube, and a suction port, which incorporates a bacterial filter, said canister being otherwise sealed and said drainage tube being connected to a porous pad of open-celled reticulated foam having more than 90% of interconnecting cells.

Other objects, features and advantages of the present invention will become evident to those skilled in the art in light of the following.

Figure 1 is a perspective view depicting the vacuum pump unit of a wound closure apparatus constructed according to the teachings of the present invention.

Figure 2 is a right side plan view depicting the vac-

uum pump unit of Figure 1.

Figure 2A is a detail view of the latch 26 portion of Figure 2, partially cut-away to eliminate guide (or "key") 29 from the view and to show portions of latch 26 in sagital cross section.

Figure 3 is a perspective view depicting a wound drainage collection canister for use in conjunction with the vacuum pump unit of Figure 1.

Figure 4 is a rear plan view depicting the wound drainage collection canister of Figure 3.

Figure 5 is a perspective view depicting the connection of a wound drainage collection canister of Figure 3 to a wound pad.

Figure 6 is a front plan view in partial cross section depicting the connection of the wound drainage collection canister of Figure 3 within the housing of the vacuum pump of Figure 1.

Figure 6A is a partial view of the apparatus shown in Figure 6 except the canister is removed.

Figure 7 is a perspective view depicting the filter carrier of the wound drainage collection canister.

Figure 8 is a top plan view depicting the filter cap of the wound drainage collection canister.

Figure 9 is a schematic view depicting the control system for a wound closure apparatus constructed according to the teachings of the present invention, and

Figure 10 is a section through a wound showing the wound pad in place.

As illustrated in Figures 1 and 2, front housing 11 and rear housing 12 connect together using any suitable means such as screws and fasteners to provide wound closure vacuum pump 10 with a small, compact, and easily portable carrying case. Consequently, front housing 11 and rear housing 12 connect together to form handle 13 that permits easy carrying of wound closure apparatus 10. Except as maybe otherwise evident from this description, the carrying case of vacuum pump 10 is substantially as described and shown in WIPO Design No. DM/032185.

Front housing 11 includes power switch 15 that is movable between an on and off position to permit user control of the delivery of power to wound closure apparatus 10. Keypad 16 and liquid crystal display (LCD) 17 mount to front housing 11 to permit the programming of wound closure apparatus 10. Chamber 18 is defined by integrally formed interior side walls 100 and 101, top wall 102, bottom wall 103 and rear wall 104. Side wall 100 is dependently attached to the interior of front housing 11 by standard mounting hardware (not shown). The would fluids collection canister, illustrated in Figures 3-5, is received within chamber 18. Side walls 100 and 101 each include a key 29 and 30, respectively, the aid in the alignment of wound fluids collection canister 19 within chamber 18. Furthermore, front housing 11 includes latch 26 to secure the wound fluids collection canister within chamber 18.

Rear housing 12 includes arm 14 pivotally mounted to it within recess 110. An identical arm pivotally mounts to the opposite side of rear housing 12 within an identical recess. Arm 14 and its corresponding arm mounted on the opposite side of rear housing 12 pivot from within their recesses to a position where they support wound closure apparatus 10 at an angle. Arm 14 and its corresponding arm angularly support wound closure apparatus 10 to permit easier user access to keypad 16. Arm 14 and its corresponding arm may also be used to permit hanging of apparatus 10 from a hospital bed foot board.

Canister 19 has a shape as shown in Figures 3 to 6. As illustrated in Figures 3 to 6, canister 19 includes sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 that define the rectangular chamber for receiving blood, pus, and other fluids emitted from a wound. Sidewalls 20 and 21 include keyways 27 and 31 respectively, that receive a respective one of keys 29 and 30 to provide easy alignment of canister 19 within chamber 18. Furthermore, keyway 27 includes recess 28 that receives latch 26 to fasten canister 19 within chamber 18.

Front wall 25 of canister 19 includes raised portion 32 extending therefrom to furnish a window that permits a user to determine the level of wound fluids within canister 19. Accordingly, raised portion 32 is transparent so that the level of wound fluids within canister 19 may be visually determined. Raised portion 32 includes sidewalls 110 and 111, top wall 112, bottom wall 113, and front face 114 that define a chamber which opens into the chamber defined by sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 of canister 19. Front face 114 of raised portion 32 includes graduations that demarcate the volume of wound fluid within canister 19. Additionally, sidewalls 110 and 111 of raised portion 32 include ridges that provide a gripping surface for the user during the insertion and removal of canister 19 from chamber 18.

Although raised portion 32 is transparent to permit the determination of the level of wound fluids within canister 19, sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, and front wall 25 are opaque or textured so that they are only translucent. As an alternative, the portions of canister 19 surrounding filter 46 may also be transparent. This enables a user to visually check for signs of contamination of filter 46. In this preferred embodiment, sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, front wall 25, and raised portion 32 of canister 19 are fabricated from a plastics material.

Canister 19 includes inlet 35 that is formed integrally with top wall 112 of raised portion 32. Inlet 35 is cylindrical in shape and communicates with the interior of canister 19 to permit the transfer of wound fluids into canister 19. In this preferred embodiment, inlet 35 is also fabricated from a plastics material.

In order to prevent liquids sucked into the canister from splashing directly onto cap 49, which masks the outlet 44, and to reduce foaming within the canister, inlet 35 has a blind inner end. Inlet 35 has a slot 35A so

that drainage fluid is deflected downwardly into the raised handle portion 32 of the canister. Handle portion 32 may communicate with the main part of the canister through one or more holes in wall 25. It is desirable to avoid foaming because this can give a false reading when a capacitance sensing device is used to sense when the canister is filled. An anti-foaming material, e.g. a silicone may be added to the canister, e.g. by coating the interior walls. It may also be advantageous to include a gel-forming substance, e.g. a polyacrylamide or modified starch in order to immobilise the drainage fluid. This is particularly useful if the apparatus is likely to be tilted.

Wound fluids (i.e. drainage) are communicated through inlet 35 into canister 19 via pad 36 and hoses 37 and 38. In this preferred embodiment, pad 36 is fabricated from an open cell polyurethane or polyether foam. Hose 37 is inserted within pad 36 by making an incision in pad 36 and inserting the end of hose 37. Hose 37 can then be secured within pad 36 using any suitable means such as an adhesive or a flange. Preferably, the foam pad is moulded or formed with an elongated hole for the drainage tube which is an interference fit with the tube. The hoses are preferably made from medical grade PVC tube. Hose 38 mounts within inlet 35 using any suitable means such as an adhesive or welding. Hoses 37 and 38 include liner lock connectors 39 and 40, respectively, (or the equivalent such as any known quick disconnect type coupling) that attach together to permit communication between hoses 37 and 38. Furthermore, hoses 37 and 38 include pinch clamps 41 and 42, respectively, that are capable of sealing their respective hose 37 or 38 to prevent the flow of wound fluids. The foam pad is preferably packaged in a sterile container together with its connector and clamp. When packaged, the clamps will be in their open condition.

The communication of wound fluids into canister 19 requires the securing of pad 36 over a wound. Pad 36 is secured over a wound using cover 43 which is fabricated from a plastics material and includes an adhesive on one side that sticks to human skin. Wound cover 43 is conveniently a surgical drape material comprising a sheet of elastomeric material coated peripherally or overall with a pressure-sensitive adhesive, such as an acrylic adhesive. The elastomeric or rubbery nature of the wound cover is important because it accommodates changes in pressure in the wound area during intermittent operation of the vacuum pump. The wound cover is preferably a polyurethane film with a removable backing sheet, i.e. of polythene to protect the adhesive surface.

A high degree of reticulation in the polymer foam is desirable to achieve good permeability when the foam is under suction. Foams having at least 90% and especially at least 95% of interconnecting cells are preferred.

In use, the foam pad is cut to a size which corresponds closely to the edge of the wound with the objective of packing the foam into the wound cavity 210 so that it contacts the surface of the cavity, rather than bridging the cavity. As depicted in Figure 10, the cavity may be extensive and there may be little or no tissue coverage to the bone 212. This is illustrated diagrammatically in Figure 10. Figure 10 is a cross-section through a wound showing the foam pad 36 packed into the wound cavity 210. It is important that the foam should be firmly packed into the recesses of the wound cavity. Drainage tube 37 terminates within the centre of the foam pad 36. Surgical drape 43 extends over the foam pad and is adhered to intact skin 211 around the periphery of the wound. Drape 43 is also firmly adhered around the tube 37 to prevent leakage of air. A wound cover is then adhered to the surrounding skin and around the drainage tube to provide an air-tight seal around the wound.

As illustrated in Figures 2, 4 and 6, canister 19 includes outlet 44 that mounts over port 45 to permit wound closure apparatus 10 to draw wound fluids into canister 19. Outlet 44 is cylindrically shaped and formed as an integral part of back wall 22 by outer wall 33 and inner wall 50 which are interconnected by end wall 34. Passageway 52, defined in part by interior wall 50 and in part by filter cap 49, provides the actual conduit for outlet 44 between the interior and exterior of canister 19. The placement of canister 19 within recess 18 such that outlet 44 resides over port 45 couples canister 19 to a vacuum pump. The vacuum pump removes air from canister 19 to create vacuum pressure within canister 19. That vacuum pressure is then transmitted to a wound site through hoses 37 and 38, thereby not only enabling therapeutic use of system 10, but also tending to promote wound drainage. Any wound drainage fluid is then drawn through pad 36 and hoses 37 and 38 into canister 19.

Outlet 44 resides near top wall 23 of canister 19 to ensure efficient operation of the vacuum pump. That is, the vacuum pump removes the most air from canister 19 when the air does not have to first bubble through wound fluids contained in canister 19. Consequently, with outlet 44 positioned near the top of canister 19, the vacuum pump removes air directly from canister 19, and it is only during the final filling of canister 19 that air must bubble through wound fluids. Preferably, as described below the apparatus includes detecting and warning means which operates before the level of the drainage fluid reaches either the inlet or outlet tube so that a fresh canister can be installed.

In removing fluids from a wound utilizing wound closure apparatus 10, a major safety concern is preventing wound fluids from contaminating the vacuum pump. Accordingly, filter 46 mounts over outlet 44 utilizing filter carrier 48 and filter cap 49 to block the flow of wound fluids to outlet 44 so that wound fluids remain within canister 19 and do not flow into the vacuum pump. In this preferred embodiment, filter 46 is a 0.2 micron hydrophobic membrane filter providing a bacterial barrier, although other filters may be substituted as appropriate.

(A) TO SHUT-OFF

As illustrated in Figure 7, filter carrier 48 includes face 53 formed integrally with lip 54. Face 53 includes groove 56 formed therein, while lip 54 supports brace 55 in its interior. Filter 46 fits within groove 56 of face 54 and is supported within filter carrier 48 by brace 55 of lip 54. An 'O' ring 53A is fitted in peripheral recess of filter carrier 48 to accommodate manufacturing tolerances and ensure a fluid tight seal in filter cap 49.

As illustrated in Figures 6 and 8, filter cap 49 includes cylindrical portions 57 and 58 which are formed integrally (with annulus 57' spanning therebetween), to hold filter carrier 48 within passageway 52 of outlet 44. To mount filter 46 over passageway 52, filter 46 is first placed within filter carrier 48 as described above. Filter carrier 48 is then positioned within filter cap 49 such that face 53 abuts annulus 57' of filter cap 49 and lip 54 of filter carrier 48 resides within annular lip 50' of outlet 44. Accordingly, when cylindrical portion 57 of filter cap 49 mounts over outlet 44, the front face 53 of filter carrier 48 and the outer edges of filter 46 abut annulus 57' to secure filter 46 within passageway 52. Filter cap 49 attaches to outlet 44 using any suitable means such as an adhesive or welding. Filter cap 49 is completely sealed except for aperture 51 positioned on top of filter cap 49. Aperture 51 communicates with port 45 via passageway 52 of outlet 44 to permit the vacuum pump to draw air from the interior of canister 19.

As illustrated in Figures 2 and 6, port 45 includes O-ring 59 mounted thereabout to provide a fluid tight seal between port 45 and inner wall 50 of outlet 44. Port 45 mounts through rear wall 104 of chamber 18 using any suitable means such as nuts 60 and 61. Furthermore, hose 62 attaches to the rear of port 45 using any suitable means such as a clamp to couple port 45 to the vacuum pump.

Switch 63 protrudes through rear wall 104 of chamber 18 to produce a signal indicating when canister 19 properly and securely resides within chamber 18. In this preferred embodiment, switch 63 is a normally open push button switch that mounts on rear wall 104 of chamber 18 using any suitable means such as a bracket. When canister 19 is properly positioned within chamber 18, its rear wall 22 presses the head of switch 63, closing switch 63 so that it provides a signal indicating that canister 19 properly resides within chamber 18.

Fill sensor 64 resides adjacent side wall 101, exterior to chamber 18. Fill sensor 64 provides a signal that indicates when canister 19 is filled with wound debris. In this preferred embodiment, fill sensor 64 is a capacitive sensor that mounts on side wall 101 of chamber 18 using any suitable means such as a bracket or appropriate adhesive material. Fill sensor 64 has a sensing profile 64A which determines the point at which the capacitance measurement is made. When wound fluids have reached the level within canister 19 which corresponds to the location of the sensing profile 64A, the capacitance within canister 19 as 'seen' by fill sensor 64 changes, resulting in fill sensor 64 outputting a signal indicating that canister 19 is filled with wound fluids to the level at which the sensing profile is located. The position of this sensing profile behind wall 101 can be changed (see Figure 6A) to provide an optimum balance of space and volume utility.

As illustrated in Figure 2A, latch 26 generally comprises latch pin 65, handle 66 latch guide sleeve 68A and spring 67. Latch pin 65 comprises a proximal end 65A and distal end 65B. Latch guide sleeve 68A abuts the inner surface of front housing 11 and is held securely in place from the outer side of front housing 11 by nut 68B. Handle 66 screws onto the proximal end 65A of latch pin 65 and is locked in position by nut 69A. In the preferred embodiment, cover 68 over nuts 69A and 68B provides a surface against which handle 66 abuts, thus preventing end 65B from excessively entering chamber 18 as will be understood further herein. Cover 68 also provides aesthetic enclosure of nuts 69A and 68B. Dependent attachment of side wall 100 (chamber 18), as described hereinabove, is such that side wall 100 abuts latch guide sleeve 68A on the side distal front housing 11. Further, this arrangement causes distal end 65B of latch pin 65 to project into chamber 18 under the force of spring 67 (shown partially cut away). Spring 67 resides circumferentially about latch pin 65 within an axial bore of latch pin guide 68A. Spring 67 exerts force between distal end 65B of latch pin 65 and an annulus within the axial bore of latch pin guide 68A. A transverse slot in the distal end of latch pin guide 68A receives end 65B of latch pin 65, providing rotational alignment of end 65B and further recess for end 65B when a user "pulls" handle 66 in an axial direction.

Latch 26 operates to ensure canister 19 remains secured within chamber 18. End 65B of latch 26 terminates in a point that protrudes through key 29 into chamber 18. During the placing of canister 19 within chamber 18, key way 27 of canister 19 forces the point 65B of the latch pin within key 29. However, once canister 19 has been properly positioned within chamber 18, recess 28 resides below latch pin end 65B so that spring 67 biases the point 65B of latch pin 65 into recess 28 to prevent the removal of canister 19 from chamber 18. The removal of canister 19 from chamber 18 is accomplished by grasping handle 66 and pulling the point 65B of latch pin 65 from recess 28. With the point of latch pin 65 no longer within recess 28, canister 19 may be pulled from chamber 18 using its raised portion 32.

As illustrated in Figure 9, wound closure apparatus 10 preferably plugs into a standard 115/120 VAC power source (e.g. an outlet) to supply power to control system 70. Alternative embodiments (not shown, although similar) are readily adapted for 220 VAC power by changing the power cord and appropriately re-wiring the tops of the transformer within the DC power supply 71 as is readily know in the art. The application of power to control system 70 is regulated by power switch 15 which is

a standard push button on/off switch. With power switch 15 depressed, DC power supply 71 receives the 115/120 VAC signal and converts it into a 12 VDC signal for use by fan 74 and motor 83. A conventional voltage regulator 96 steps down the voltage to +5V or 12V for use by each of the other DC components 63, 16, 17, 82, 72 and 75. Voltage regulator 96 connects to keypad 16, LCD 17, switch 63, microcontroller 72, transducer 75, and tilt sensor 82 to supply each of them with the +5V DC signal. Microcontroller 72 links to solid state relays (MOSFETs) 97 and 98 for controlling the provision of the 12 VDC power supply to fan 74, pump motor 83 and fill sensor 64, respectively.

As illustrated in Figure 1, once power switch 15 is depressed, a user employs keypad 16 and LCD 17 to select the operating parameters for wound closure apparatus 10. Wound closure apparatus 10 stores the previously selected operating parameters so that upon power initialization, LCD 17 displays the phrase "NEW PATIENT" with the word "NO" over arrow button 76, and the word "YES" over arrow button 77. If the user presses arrow button 76 to answer no, wound closure apparatus 10 will operate at the previously selected parameters. After answering no, the user presses on/off button 78 to begin operation of wound closure apparatus 10.

Conversely, if the user presses arrow button 77 to indicate a new patient, wound closure apparatus 10 will operate either under default values or allow the user to select the operating parameters. To operate under default parameters, the user presses on/off button 78 after pressing arrow button 77. However, to select his or her own values, the user presses option button 79 after pressing arrow button 77.

Upon the pressing of option buttons 79, LCD 17 displays a bar graph representing the spectrum of available vacuum pump pressures and a numerical representation of the vacuum pump pressure presently displayed by the bar graph. The user changes vacuum pump pressure using arrow buttons 76 and 77. The pressing of arrow button 76 reduces vacuum pump pressure, while the pressing of arrow button 77 increases vacuum pump pressure. After selecting the desired vacuum pump pressure, the user presses option button 79 to save the selected vacuum pump pressure.

Once the selected vacuum pump pressure has been saved, LCD 17 displays the pump operation times available to the user. The user may program wound closure apparatus 10 to pump either continuously or intermittently. Thus, LCD 17 displays the word "CONTINUOUS" over arrow button 76 and "INTERMITTENT" over arrow button 77. The user selects continuous operation by pressing arrow button 76 followed by on/off button 78 to activate the vacuum pump. In its continuous mode, wound closure apparatus 10 runs its vacuum pump continuously until on/off button 78 is pressed again.

If the user presses arrow button 77 to select intermittent operation, LCD 17 displays a bar graph or figures representing the minimum and maximum on times for the vacuum pump. LCD 17 also displays the phrase "ON TIME" and the numerical value presently displayed. A user decreases the on time of the vacuum pump by pressing arrow button 76 and increases the on time of the vacuum pump by pressing arrow button 77. After selecting the desired on time, the user presses options button 79 to save the selected on time value.

LCD 17 then displays a second bar graph or figures representing the off time for the vacuum pump with the phrase "OFF TIME" and the numerical value presently depicted by the bar graph. Again, arrow buttons 76 and 77 are pressed to increase or decrease, respectively, the off time for the vacuum pump. After selecting the off time, the user presses options button 79 followed by on/off button 78 to operate wound closure apparatus 10 using the selected parameters.

Keypad 16 includes setting button 80 to permit the user to sequentially display the currently selected operating parameters of wound closure apparatus 10. Keypad 16 further includes delay button 81 to permit the user to deactivate an alarm sounded in response to an improper operating condition of wound closure apparatus 10. Delay button 81 provides the user with the ability to silence alarms so that the alarm will not have to be listened to during the correction of the problem.

Any new alarm conditions occurring within the fifteen minute period ("delay period") after the pressing of delay button 81 will not be indicated by an audible alarm. However, the pump will still be deactivated when appropriate, even during the delay period.

Again referring to Figure 9, microcontroller 72 is a multi-port microprocessor with a eight-bit analog to digital (A/D) converter having associated memory that stores the program directing microcontroller 72 during its control of wound closure apparatus 10. After receiving and storing the user selected operational parameters and receiving an on signal due to the pressing of on/off button 78, microcontroller 72 activates pump motor 83 which, in turn, drives vacuum pump 84 to begin the removal of air from canister 19.

As vacuum pump 84 operates, it draws air from within canister 19, into hose 62 via outlet 44 of canister 19 and port 45. Hose 62 connects to filter 85 and transducer 75 via T-junction 91. Filter 85 is similar to filter 46 and thus ensures no wound fluids contaminate vacuum pump 84. Filter 85 communicates with pump 84 via T-junction 88 and one arm of the latter is connected to bleed valve 86. Bleed valve 86 communicates with the atmosphere to release pressure developed within line 62 by vacuum pump 84 after microcontroller 72 deactivates vacuum pump 84. Bleed valve 86 is sufficiently small to ensure that it generally does not affect the vacuum pressure levels achieved by vacuum pump 84 as it evacuates air from canister 19, except to prevent over pressurisation beyond 33,3 kPa (250 mmHg) and to

prevent erratic operation of the vacuum pump at very low pressure settings..

In the preferred embodiment, an orifice of 0.5 mm diameter is especially preferred for bleed valve 86. Valve 86 or the equivalent is particularly important for enabling intermittent application of negative pressure, as the orifice allows for gradual release of the negative pressure (over a period of about fifteen seconds) when the pump motor 83 is de-actuated. Bleed valve 86 is positioned outside housing 11 to facilitate un-clogging of aperture 86 in the event of a blockage. An aperture is provided in bleed valve 86, which is machined from stainless steel. Flow control orifices would be alternatives.

Line 62 also includes T-connector 91 to connect it with line 92. Line 92 is connected to tank 94 which acts as a damper to pressure changes in line 62. This dampening effect, facilitated by restrictor 89 in line 93 between transducer 75 and T-junction 91, causes the pressure measured by transducer 75 to be an accurate indication of actual wound site pressure. Transducer 75 communicates with line 62 via line 93 to measure tank 94 pressure and produce an electrical signal representative of that pressure. Transducer 75 outputs its pressure signal to microcontroller 72.

Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83. As previously described, the user selects either a default vacuum pump pressure or a desired vacuum pump pressure for the operation of wound closure apparatus 10. After receiving the wound pressure signal from transducer 75, microcontroller 72 compares the wound pressure with the user selected pressure. If the wound pressure is higher than the user selected vacuum pump pressure, microcontroller 72 reduces pump motor speed to decrease vacuum pump pressure and thus the pressure at the wound. Conversely, if the wound pressure is less than the user selected vacuum pump pressure, microcontroller 72 increases the speed of pump motor 83 resulting in an increase in the vacuum pressure applied at the wound.

Microcontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83. That is, microcontroller 72 receives the 12V DC signal from DC power supply 71 and outputs a voltage between 0 and 12V DC to pump motor 83 to control its speed in accordance with the user selected vacuum pump pressure value. Accordingly, microcontroller 72 employs feedback to ensure that the wound experiences the user selected vacuum pump pressure. If the target pressure is not reached after a period of five minutes, microcontroller 72 deactivates motor 83 and sounds the audible alarm. Additionally, the feedback signal prevents maximum vacuum pump pressure from being exceeded. If the wound pressure measured by transducer 75 exceeds a maximum safe vacuum pump pressure, microcontroller 72 deactivates pump motor 83.

Wound closure apparatus 10 includes fan 74 to cool pump motor 83 and printed circuit board or chassis 200 during the operation of the wound closure apparatus 10. In the preferred embodiment, microcontroller 72 controls fan 74 to always operate while power is being supplied. In alternative embodiments, however, microcontroller 72 controls fan 74 to operate only in relation to motor 83, because it is only necessary for fan 74 to operate if motor 83 is also operating. In such alternative, as long as pump motor 83 operates, microcontroller 72 runs fan 74. However, when microcontroller 72 deactivates pump motor 83 it also deactivates fan 74.

Control system 70 includes fill sensor 64 to provide a signal to microcontroller 72 that indicates when canister 19 is completely filled with wound fluids. After receiving a signal from fill sensor 64, microcontroller 72 deactivates pump motor 83 and fan 74 and activates alarm 95 to signal the user that canister 19 must be replaced.

Control system 70 includes switch 63 to prevent users from operating wound closure apparatus 10 without a canister properly installed. If a canister is not properly installed, switch 63 remains open and therefore outputs no signal to microcontroller 72. If microcontroller 72 receives no signal from switch 63, indicating no canister within chamber 18, it will not supply power to pump motor 83 even after a user has pressed on/off button 78. Furthermore, microcontroller 72 activates alarm 95 to signal the user that either a canister is not properly installed or is improperly installed within chamber 18 when therapy is activated. Microcontroller 72 operates pump motor 83 only if switch 63 is depressed to provide a signal indicating the proper placement of a canister within chamber 18.

Control system 70 includes tilt sensor 82 to prevent operation of wound closure apparatus 10 if it is tilted excessively. Excessive tilting of wound closure apparatus 10 during operation diminishes the efficiency of removal of wound fluids and, more importantly, might result in either the contamination of vacuum pump 84 or the spilling of wound fluids. Thus, if wound closure apparatus 10 tilts along any of its axes beyond a predetermined angle (approximately 45° in this preferred embodiment), tilt sensor 82 outputs a signal to microcontroller 72. In response, microcontroller 72 deactivates pump motor 83 and activates alarm 95 to signal the user of the excessive tilt situation. In this preferred embodiment, tilt sensor 82 may be implemented with any standard mercury switch. The tilt circuiting and alarm operates as follows. If therapy is in progress and the pump unit is tilted, the alarm will sound and the liquid crystal display 17 will state 'unit tilted'. Therapy is automatically stopped. When the unit is returned to the vertical, therapy will be automatically reinstated after a time delay (e.g. about 30 seconds) has elapsed..

Claims

1. A canister (19) for use in wound treatment apparatus comprising a wound dressing pad (36) and a suction pump (10) for applying negative pressure to the wound dressing pad, said canister comprising a moulded plastics container (19) having an inlet (35) for connection to a wound dressing pad and an outlet (52) for connection to a suction pump, said outlet incorporating a bacterial filter (46).

2. A canister as claimed in claim 1, which includes deflector means (35A) for deflecting liquid sucked through the inlet in a direction towards the bottom of the canister.

3. A canister as claimed in claim 1 or 2, which includes an anti-foaming substance.

4. A canister as claimed in any one of claims 1 to 3, which includes a gel-forming substance, which is capable of immobilising drainage fluids within the canister.

5. A sealed sterile pack for use in wound treatment apparatus, which comprises a canister (19) for collecting fluids sucked from a wound, said canister having an inlet (35), which is sealed to a drainage tube (38), and a suction port (52), which incorporates a bacterial filter (46), said canister being otherwise sealed and said drainage tube being connected to a porous pad (36) of open-celled reticulated foam having more than 90% of interconnecting cells.

6. A pack as claimed in claim 5, wherein said foam comprises more than about 95% interconnecting cells.

7. A pack according to claim 5 or 6, wherein the drainage tube is fitted into the foam by an interference fit.

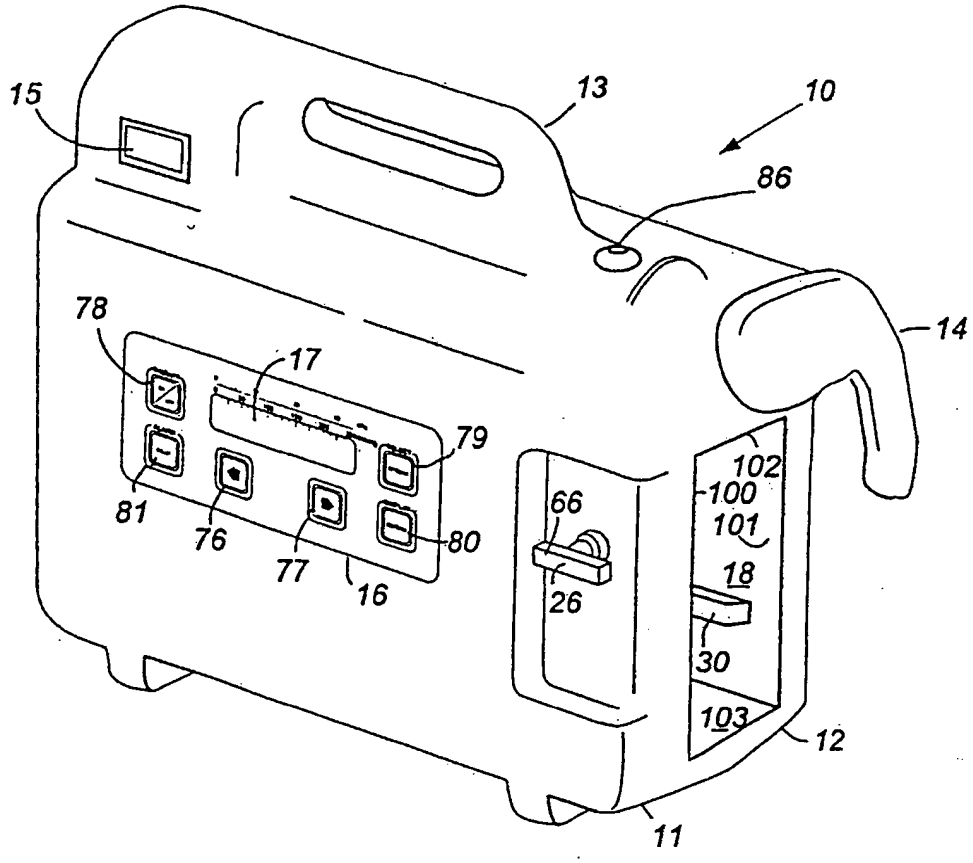
15
13
10
86
14
78
17
79
81
76
77
80
16
66
26
102
100
101
18
30
103
12
11

FIG.1

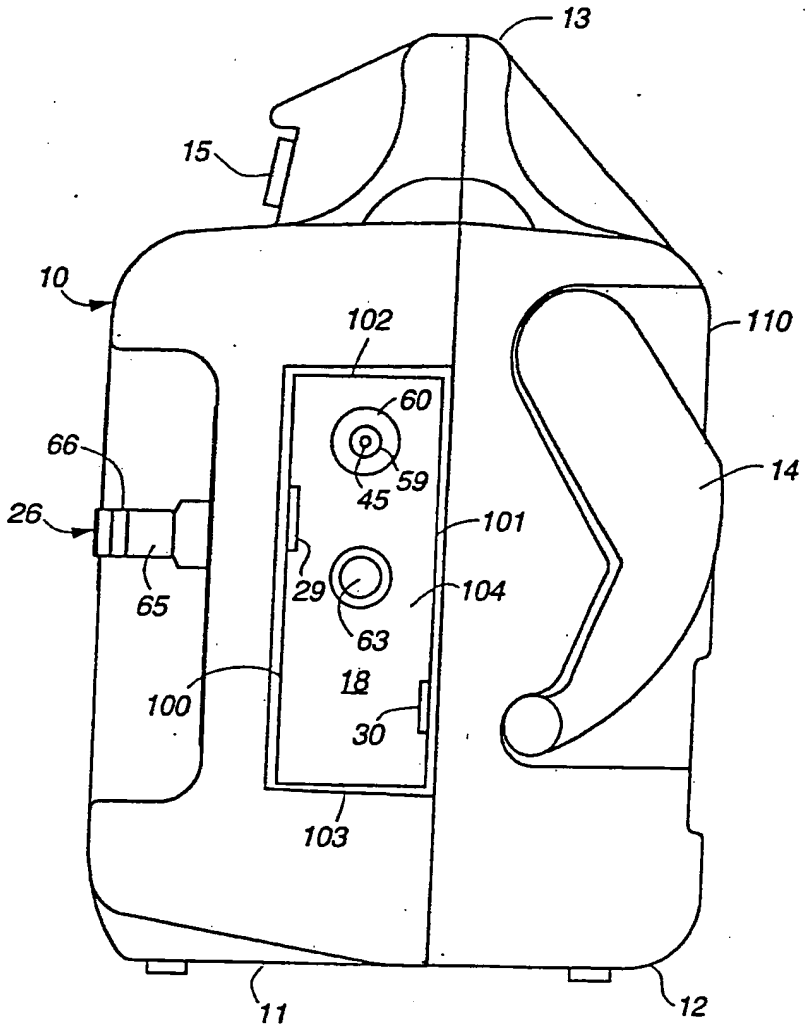
13
15
10
102
110
60
66
59
45
14
26
101
29
104
65
63
18
100
30
103
11
12

FIG.2

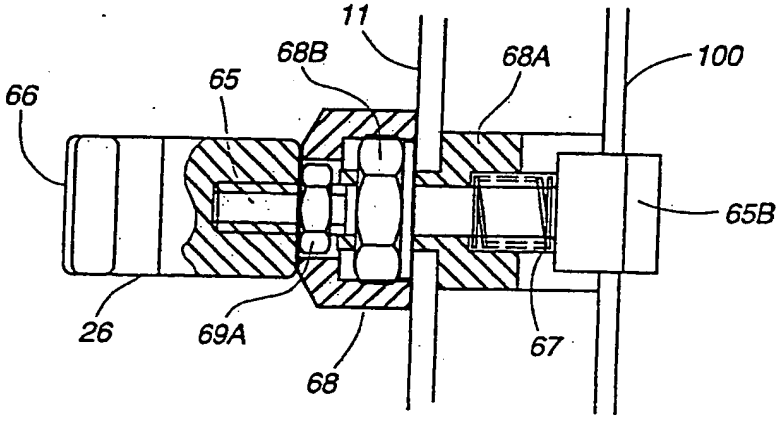
11
68B
68A
100
66
65
65B
26
69A
67
68

FIG.2A

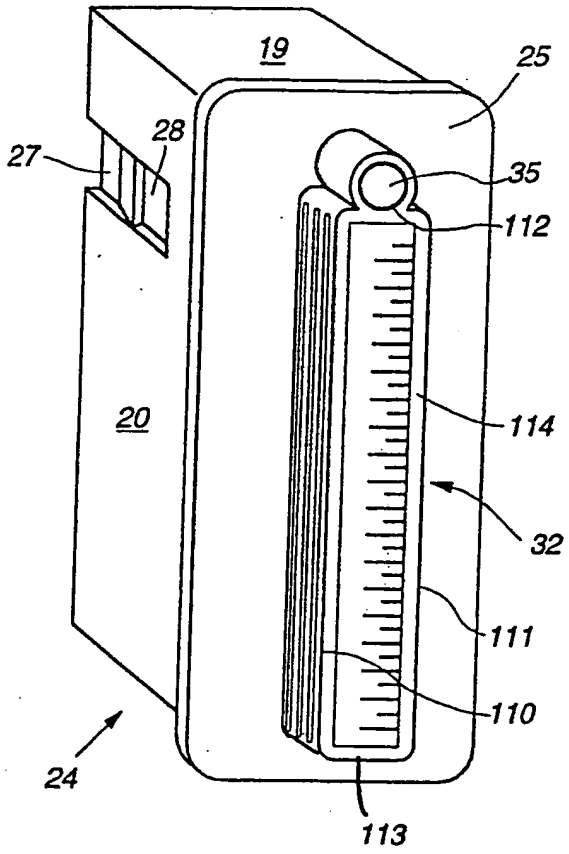
19
25
28
27
35
112
20
114
32
111
110
24
113

FIG.3

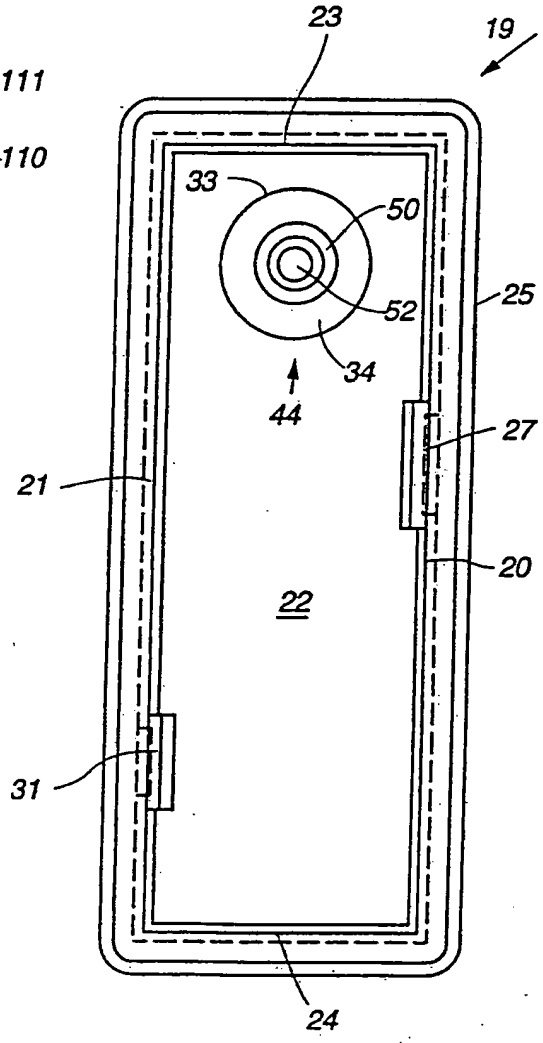
23
19
33
50
25
52
34
44
27
21
20
22
31
24

FIG.4

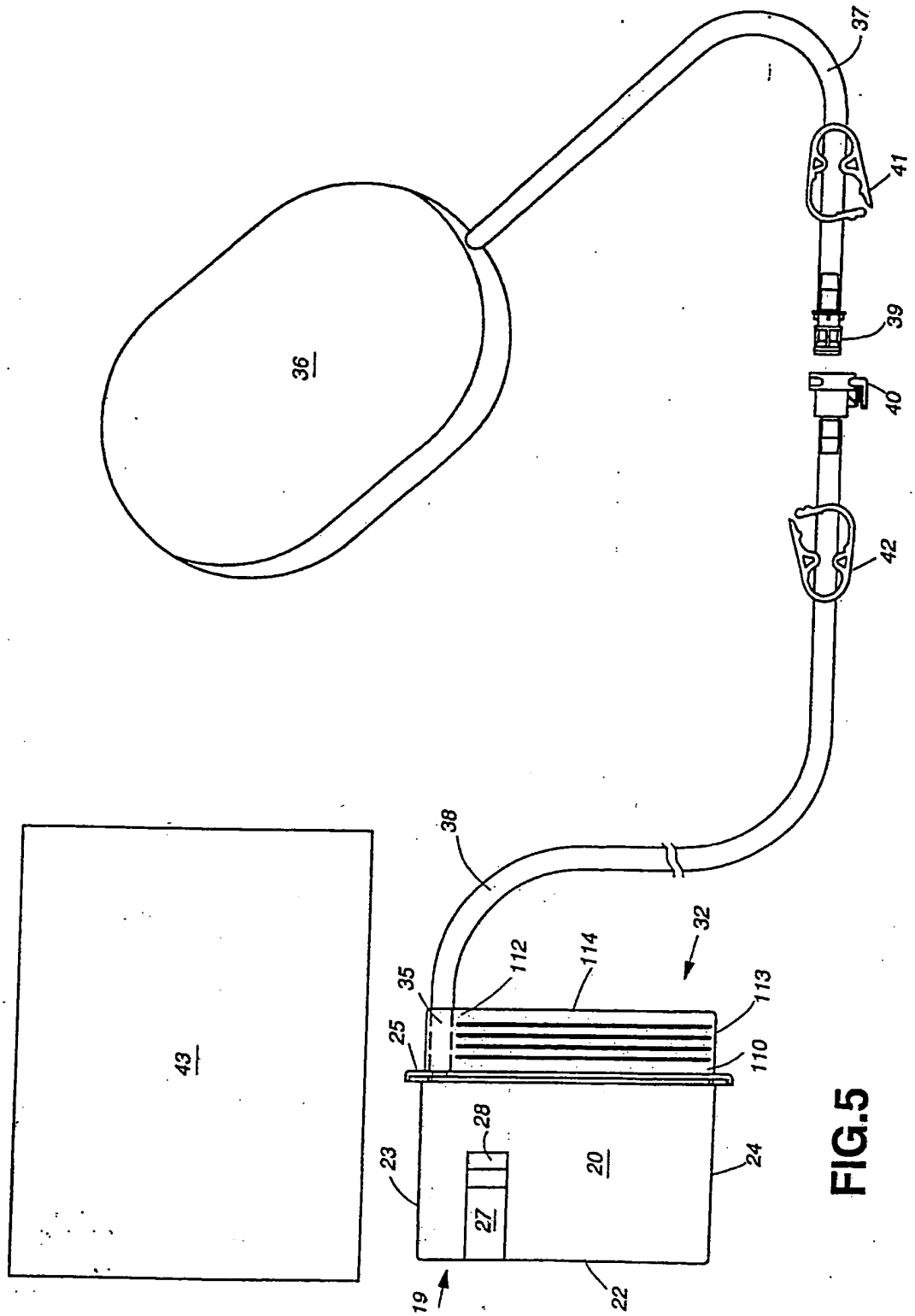

FIG.5

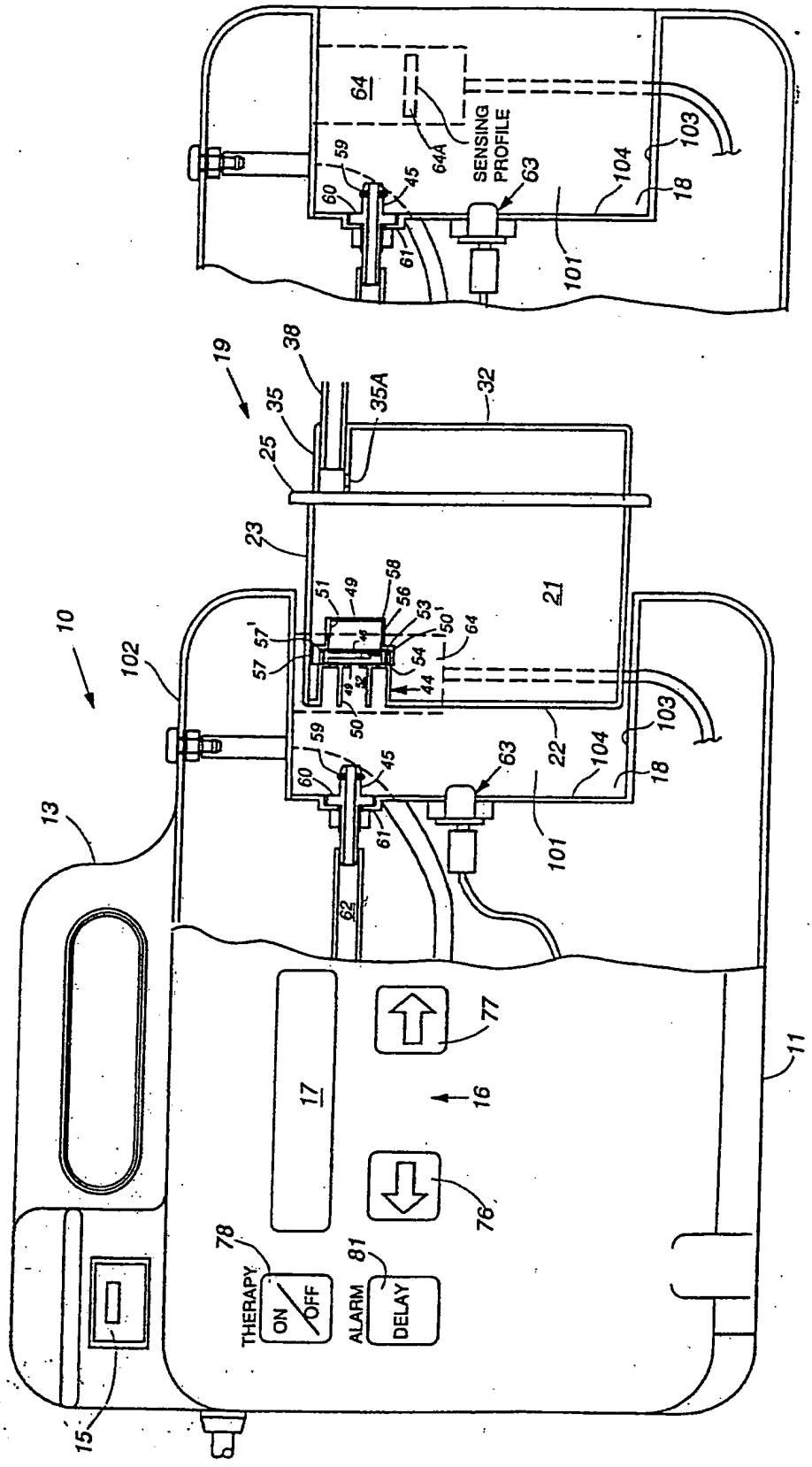

FIG.6

FIG.6A

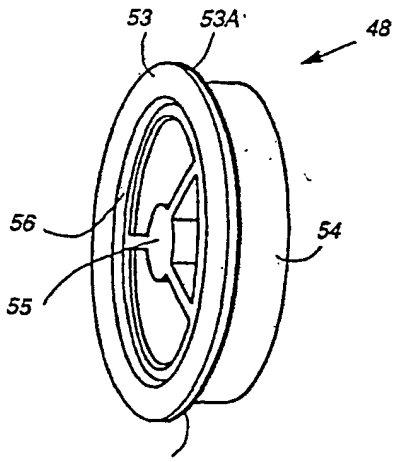

FIG.7

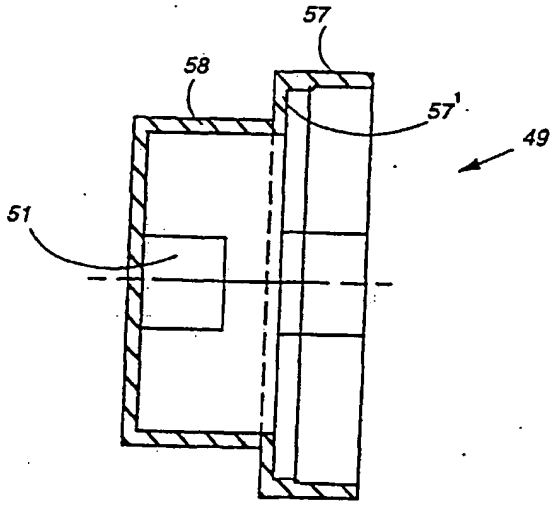

FIG.8

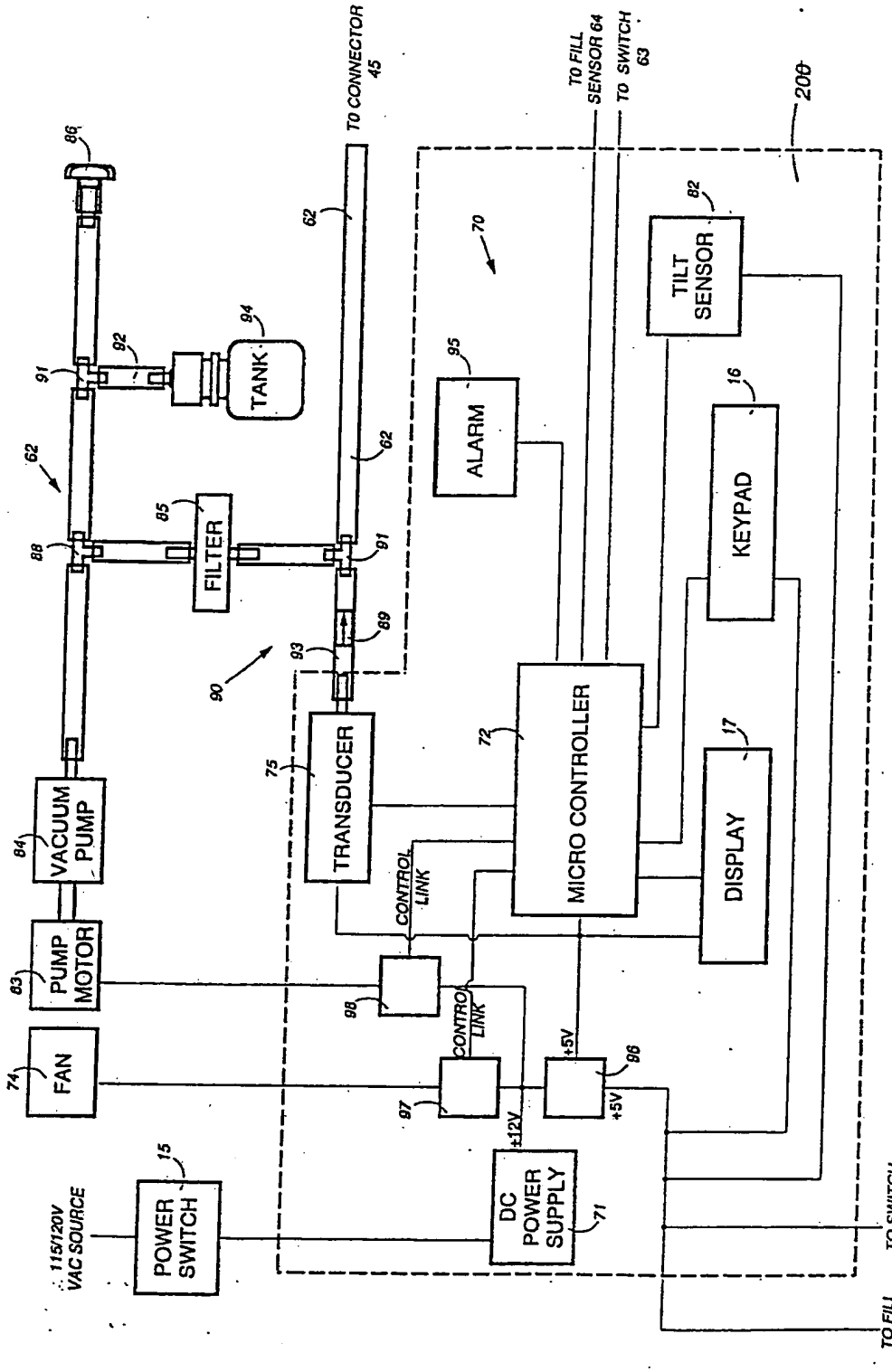
TO CONNECTOR 45
TO FILL SENSOR 64
TO SWITCH 63
200
86
62
70
82
TILT SENSOR
94
TANK
92
91
95
ALARM
16
KEYPAD
62
85
FILTER
88
91
89
90
93
72
MICRO CONTROLLER
75
TRANSDUCER
17
DISPLAY
84
VACUUM PUMP
CONTROL LINK
63
PUMP MOTOR
98
CONTROL LINK
+5V
96
74
FAN
97
+12V
+5V
15
115/120V VAC SOURCE
POWER SWITCH
DC POWER SUPPLY
71
TO SWITCH 63
TO FILL SENSOR 64

FIG.9

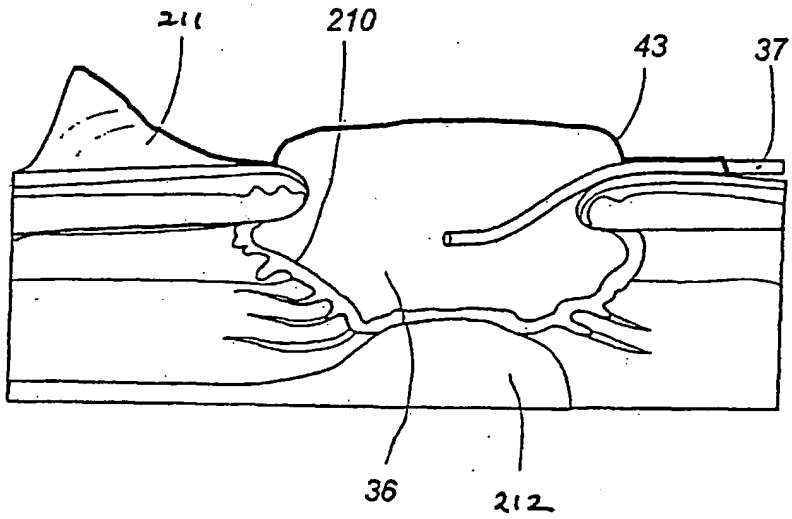

FIG.10

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 20 0529

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X Y	US 3 520 300 A (FLOWER GUILES JR) 14 July 1970 * column 2, line 10 - column 3, line 16; figures *	1,5-7 2-4	A61M1/00
Y	EP 0 358 302 A (SMITHS INDUSTRIES PLC) 14 March 1990 * abstract; figures 1,4 * * column 2, line 26 - column 4, line 34 *	2	
Y	US 5 092 858 A (BENSON C DAVID ET AL) 3 March 1992 * abstract; figures 1-6 * * column 4, line 33 - column 5, line 27 *	3,4	
A	US 5 215 522 A (PAGE ET AL.) 1 June 1993 * abstract; figures 1-3 * * column 1, line 55 - line 68 *	5	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	7 April 1998	Zeinstra, H

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Hunt et al. WO 97/18007

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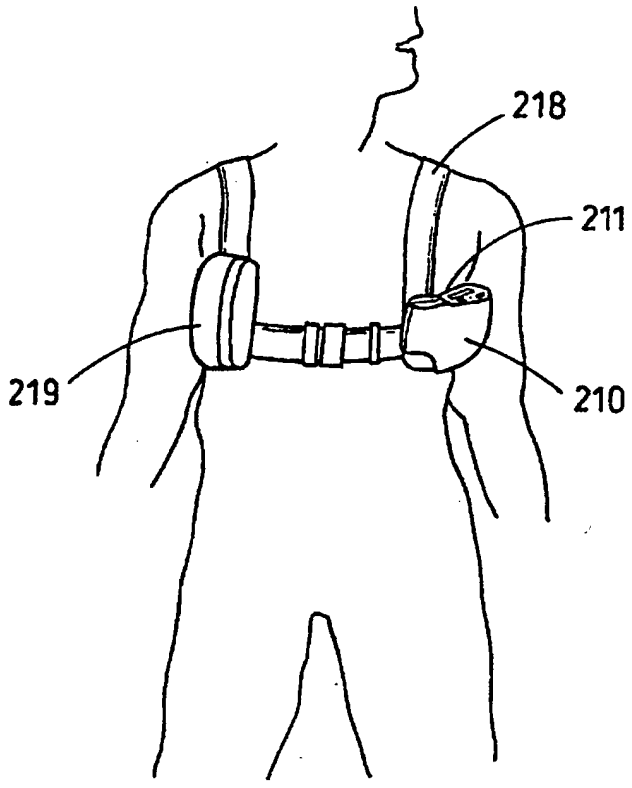
(54) Title: PORTABLE WOUND TREATMENT APPARATUS

(57) Abstract

The invention relates to a portable wound treatment apparatus for stimulating the healing of superficial wounds. The apparatus comprises a housing (210) containing a suction pump and a canister for containing fluids drawn from the wound. The housing is supported on a harness or belt (216, 218) worn by the patient and is connected to a porous dressing at the wound site by a catheter.



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PORTABLE WOUND TREATMENT APPARATUS

This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile it means that he or she would be confined for long periods while the treatment takes place.

An object of this invention is therefore to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

According to one aspect of the present invention there is provided a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including

means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

Typically, the housing will have a curved surface on the side intended to be supported against the person's body so as to make the apparatus more comfortable to wear. In addition, controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above PCT application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a

predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of the apparatus in accordance with the invention,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

Figures 6A to D show various views of a foam dressing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube,

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig in to the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A the housing 210 is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister

spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in manner to be described later. By means of tube 106 and transducer 108 the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the

canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lypophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by

an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

In an alternative embodiment, the multi-lumen tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

Figure 5E is a plan view of the top of a preferred shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with respectively conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5F. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for

a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

Figures 6A~6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity is formed around the wound.

In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed

by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705,706, which are not coated with adhesive, to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound re-sutured. This therapy improves the rate of granulation and healing of wounds after surgery.

CLAIMS:-

1. A portable therapeutic apparatus for stimulating the healing of a superficial wound in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

2. Apparatus as claimed in claim 1 wherein the housing has a curved surface on the side intended to be supported against the person's body, and controls located on an upper side of the housing.

3. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and a filter barrier located in the canister at the outlet side, and pressure detecting means arranged to detect pressure changes in the tube between the canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

4. Apparatus as claimed in claim 3 wherein the filter barrier covers the entire outlet from the canister and the dimensions of the pores in said barrier are such that when liquid covers substantially the whole of the filter barrier, said pressure detecting means signals a sharp increase in negative pressure in the tube connecting the canister with the pump.

5. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and at least one filter interposed between the canister and the pump, said apparatus including an additional conduit connecting the porous pad to pressure detecting means whereby the pressure substantially at the wound site can be monitored.

6. Apparatus as claimed in claim 5 which includes a relief valve for admitting air to the additional conduit and means for controlling the operation of the valve so that intermittent suction can be applied to the wound site.

7. Apparatus as claimed in claim 5 or 6 in which a single tube links the porous pad with the housing, said tube being longitudinally partitioned to provide a conduit for applying suction and an additional conduit for connection to said pressure detecting means.

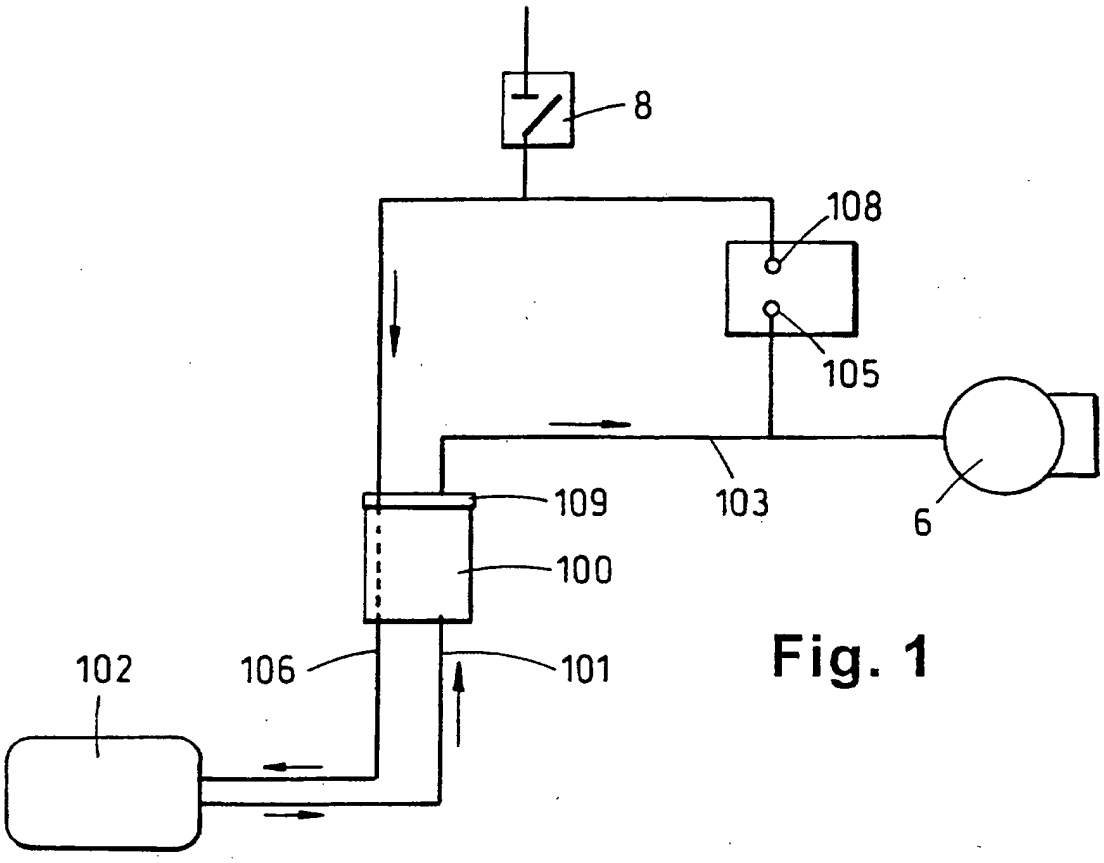

Fig. 1

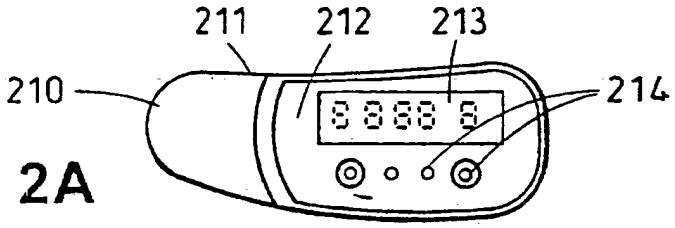

Fig. 2A

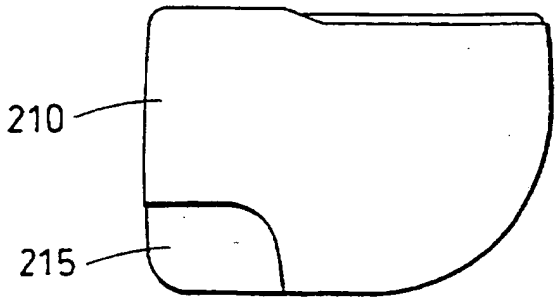

Fig. 2B

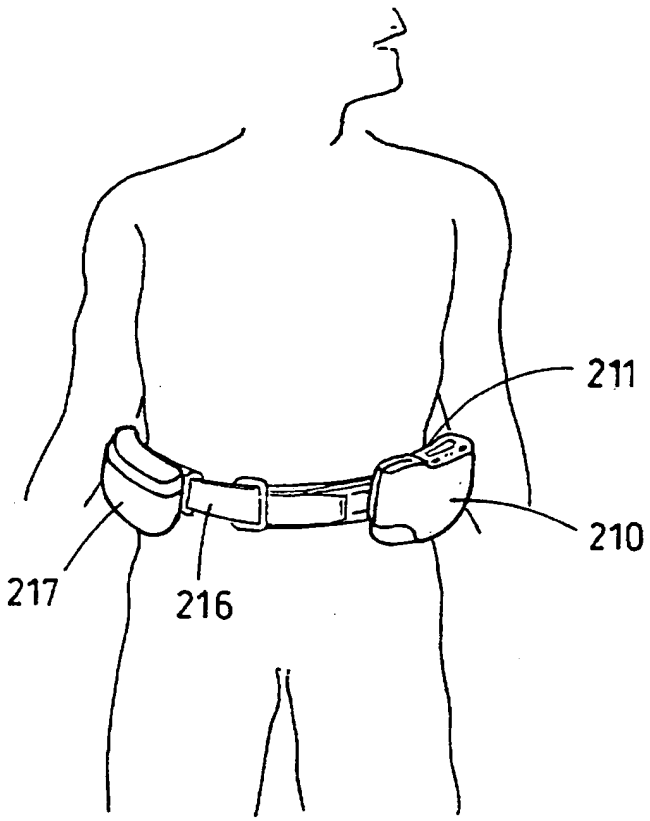

Fig. 3A

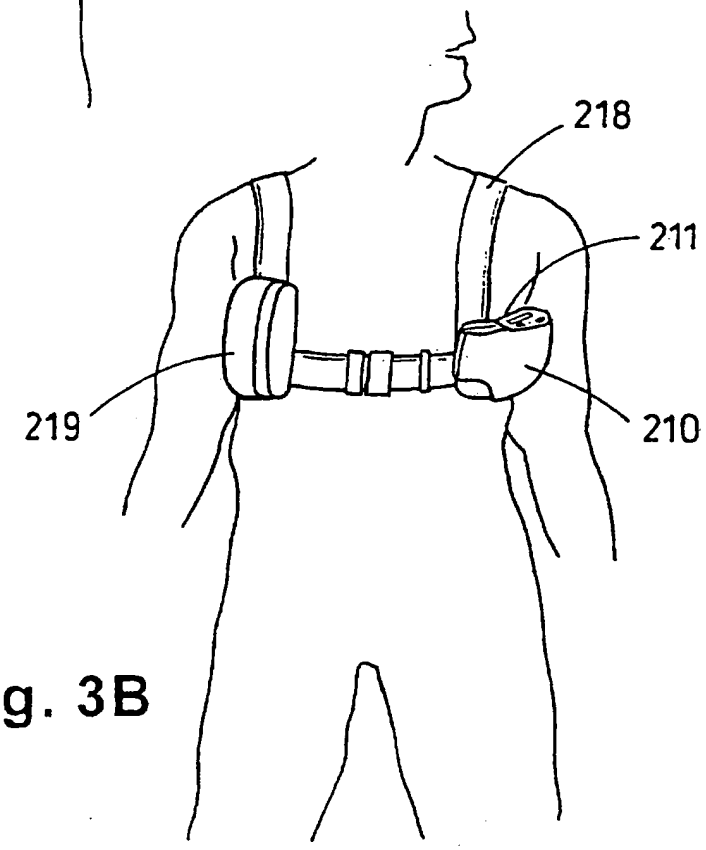

Fig. 3B

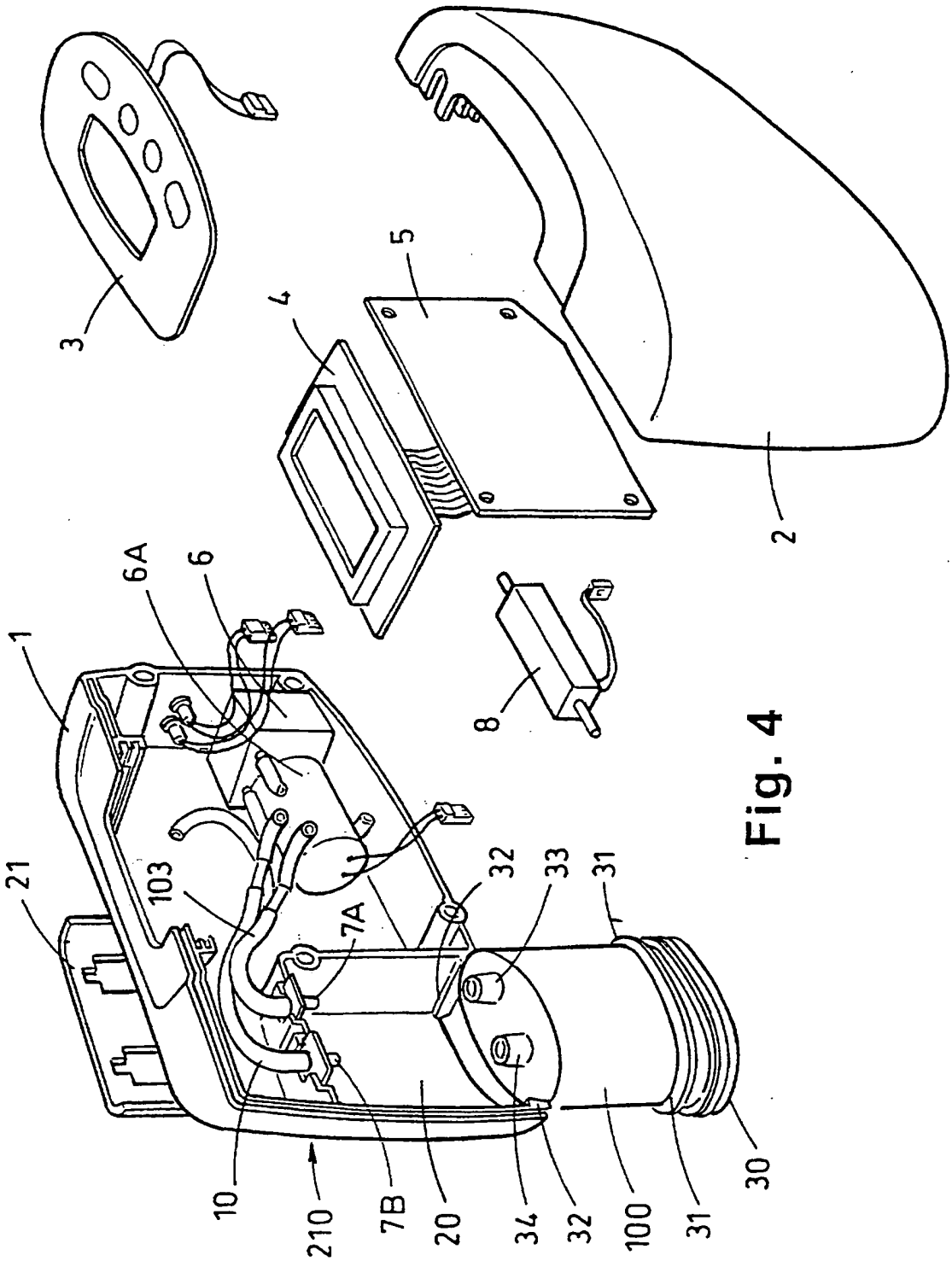

Fig. 4

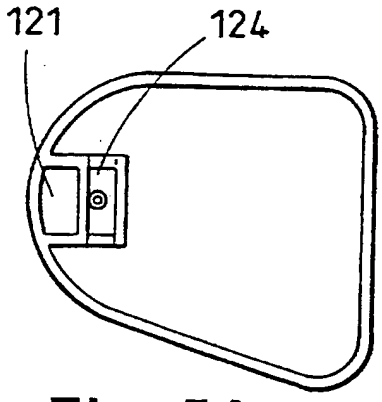

Fig. 5A

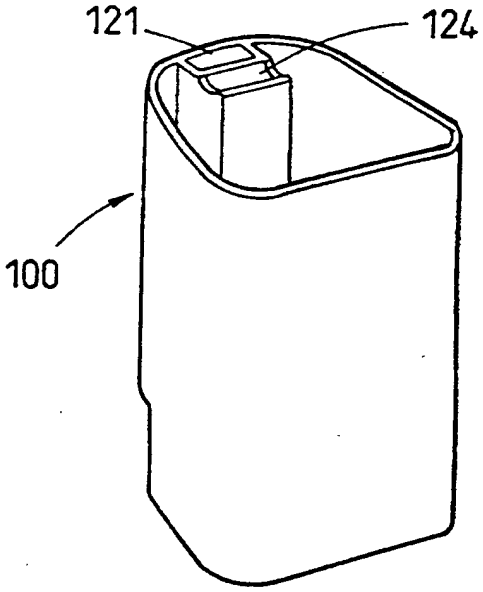

Fig. 5D

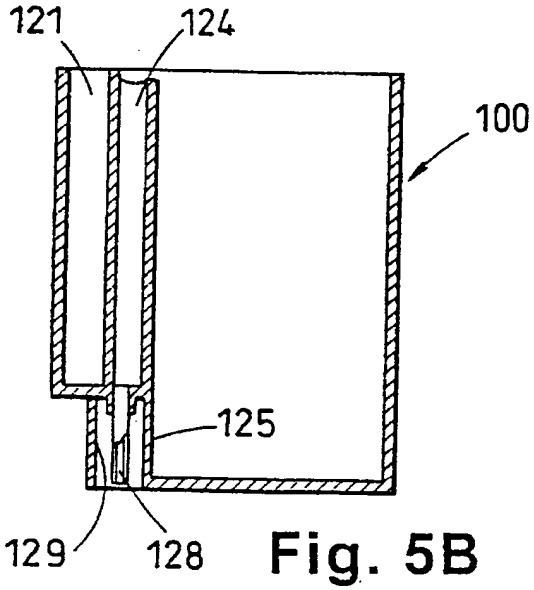

Fig. 5B

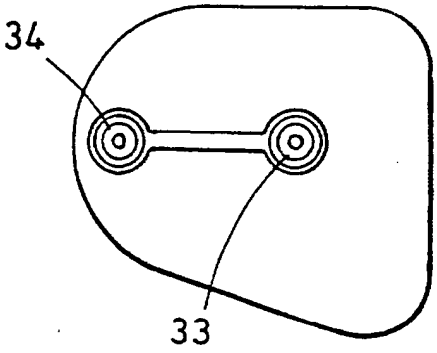

Fig. 5E

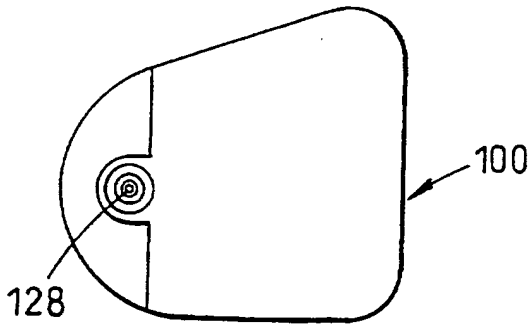

Fig. 5C

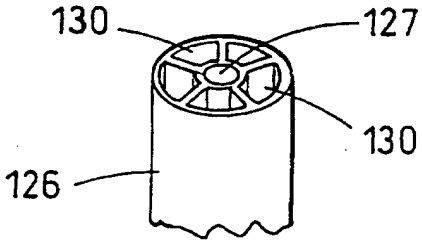

Fig. 5F

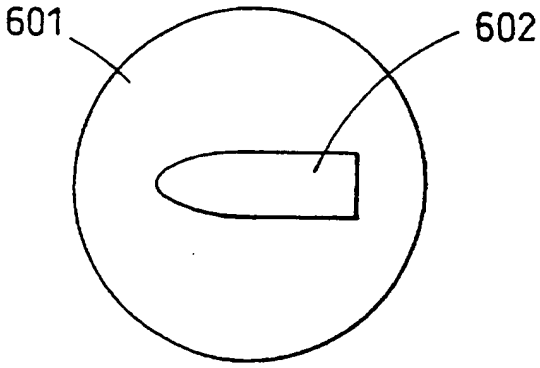

Fig. 6A

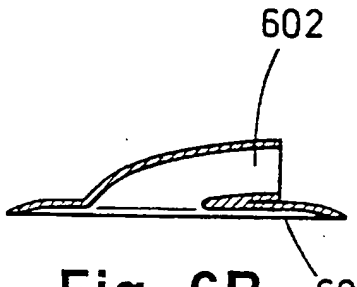

Fig. 6B

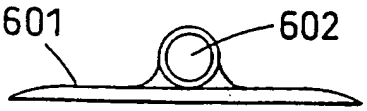

Fig. 6C

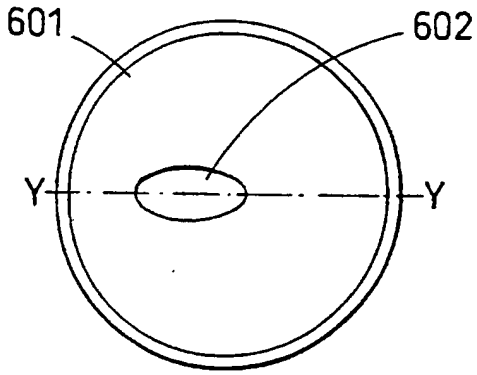

Fig. 6D

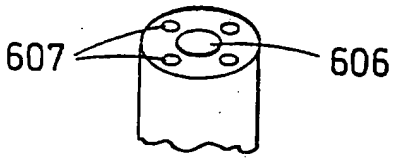

Fig. 6E

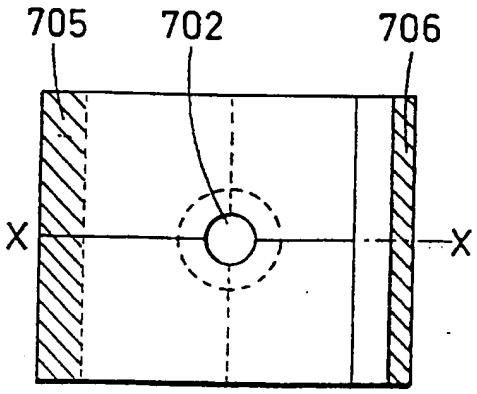

Fig. 7A

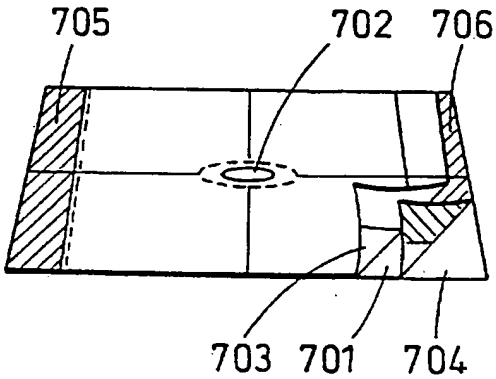

Fig. 7B

INTERNATIONAL SEARCH REPORT

I ational Application No
PCT/GB 96/02802

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M27/00 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 134 994 A (SAY) 4 August 1992 see column 1, line 7 - line 9 see column 2, line 6 - column 4, line 2 see figures 1,4-8	1
Y		2

Y	WO 80 02182 A (MOSS) 16 October 1980 see page 4, line 23 - line 31 see figure 1	2

X	US 4 710 165 A (MCNEIL ET AL.) 1 December 1987 see column 5, line 1 - line 56	1

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
17 April 1997	29.04.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Schönleben, J

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 96/02802

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 94 20041 A (WAKE FOREST UNIVERSITY) 15 September 1994 see page 12, line 8 - page 17, line 8 see page 18, line 2 - line 35 see figures 1,8	3-7
A		5
Y	DE 295 04 378 U (MTG) 14 September 1995 see the whole document	3,4
Y	DE 43 06 478 A (WAGNER) 8 September 1994 see column 2, line 8 - line 16 see column 4, line 66 - column 5, line 65 see figures 1-5	5-7
A	GB 2 220 357 A (SMITHS INDUSTRIES) 10 January 1990 see page 7, line 1 - page 8, line 20 see figure 1	3
A	GB 2 235 877 A (ANTONIO TALLURI) 20 March 1991 see page 4, line 12 - page 5, line 18 see figures 2-4	3
A	US 3 066 672 A (CROSBY ET AL.) 4 December 1962 see column 1, line 67 - column 2, line 35 see figures 1,3	6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 96/02802

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

SEE ANNEX

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

National Application No
PCT/GB 96/02802

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5134994 A	04-08-92	NONE	
WO 8002182 A	16-10-80	US 4266545 A	12-05-81
		EP 0026226 A	08-04-81
		JP 56500360 T	26-03-81
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		EP 0688189 A	27-12-95
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US 3066672 A	04-12-62	NONE	